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Nos. 22-2069, -2070, -2071, -2072

IN THE
United States Court of Appeals
FOR THE FEDERAL CIRCUIT

MASIMO CORPORATION,

Appellant,

v.

APPLE INC.,

Appellee.

APPEAL FROM THE PATENT TRIAL AND APPEAL BOARD
CASE NOS. IPR2021-00193, IPR2021-00195, IPR2021-00208, IPR2021-00209

JOINT APPENDIX

Joseph R. Re, *Principal Counsel*
Stephen C. Jensen
Jarom D. Kesler
Stephen W. Larson
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614
(949) 760-0404

Jeremiah S. Helm
KNOBBE, MARTENS, OLSON & BEAR, LLP
1717 Pennsylvania Ave., N.W.
Washington, D.C. 20006
(202) 640-6400

*Attorneys for Appellant
Masimo Corporation*

Lauren A. Degnan, *Principal Counsel*
Christopher Dryer
W. Karl Renner
FISH & RICHARDSON P.C.
1000 Maine Ave., Suite 1000
Washington, DC 20024
Tel: (202) 783-5070

Ashley Bolt
FISH & RICHARDSON P.C.
1180 Peachtree Street NE
21st Floor
Atlanta, GA 30309
Tel: (404) 892-5005

Attorneys for Appellee Apple Inc.

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FIG. 1 (a)

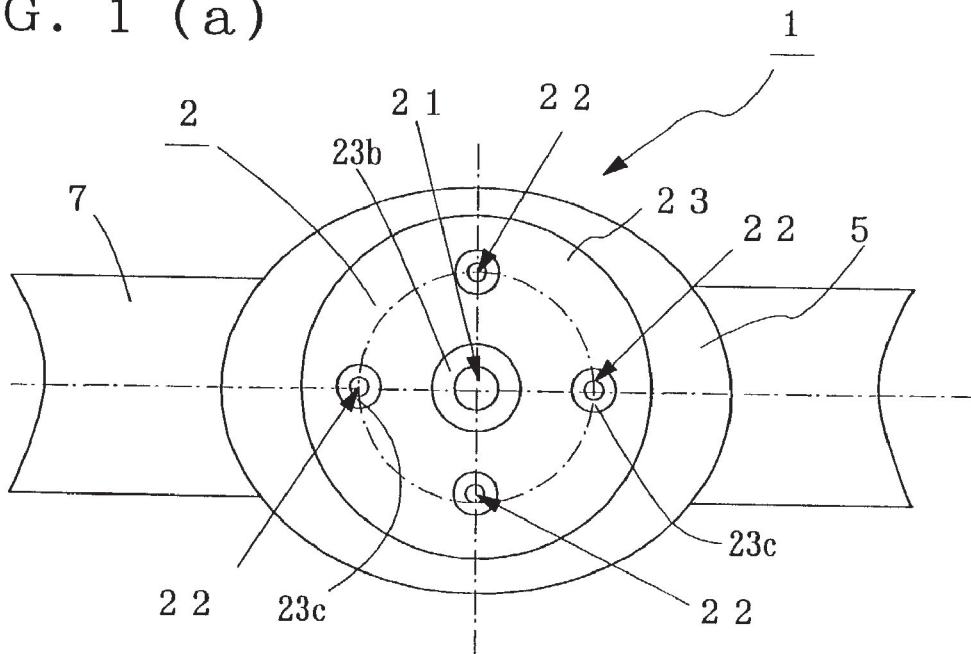


FIG. 1 (b)

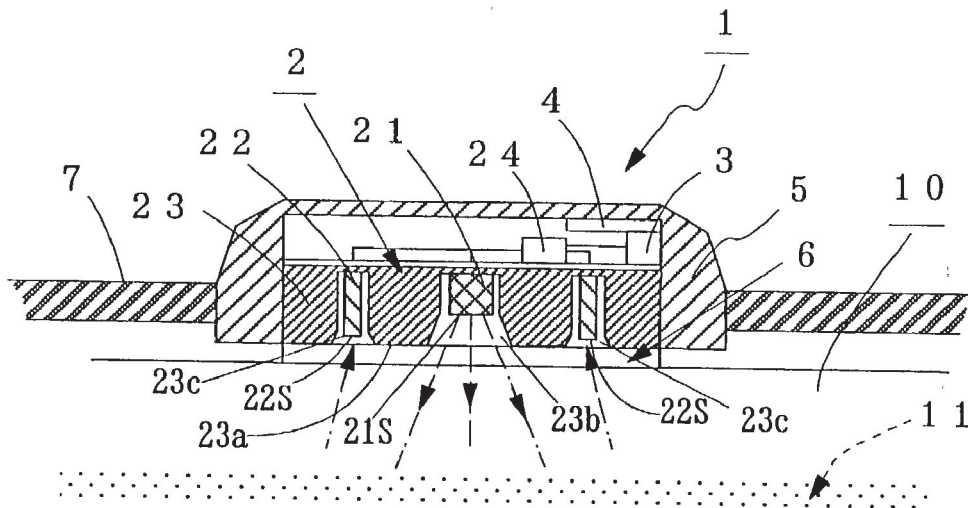


FIG. 2

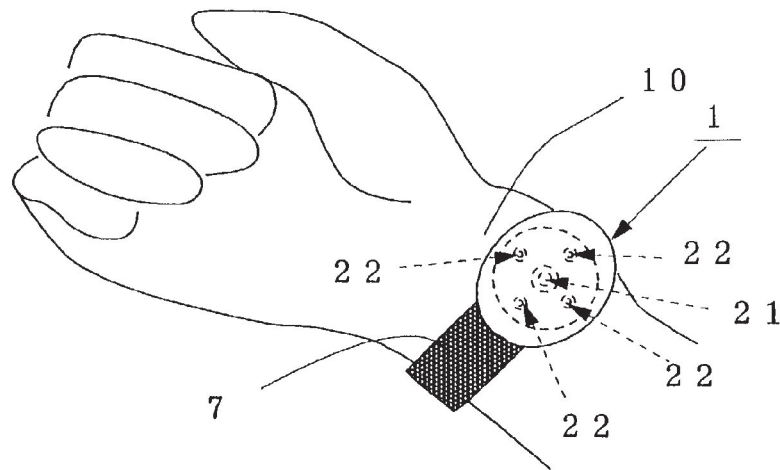


FIG. 3

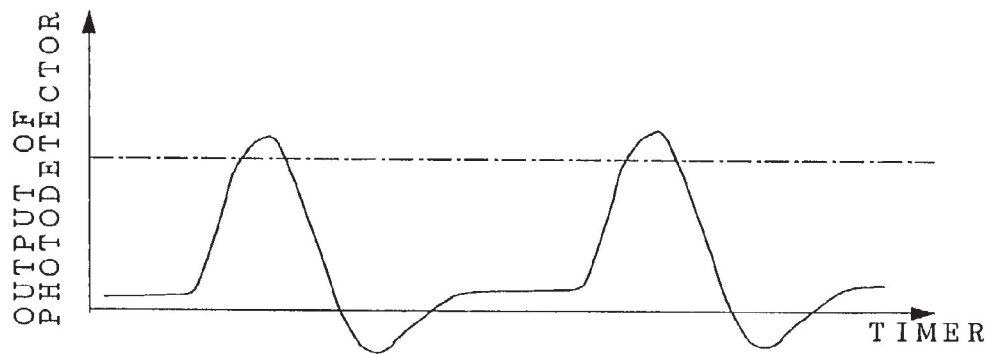


FIG. 4 (a)

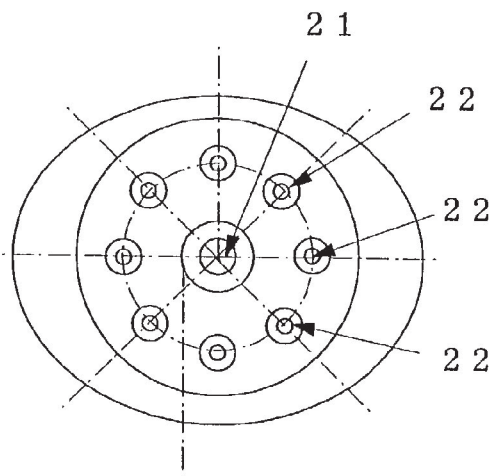


FIG. 4 (b)

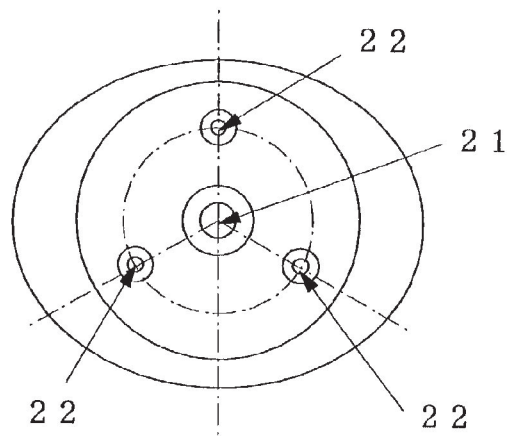
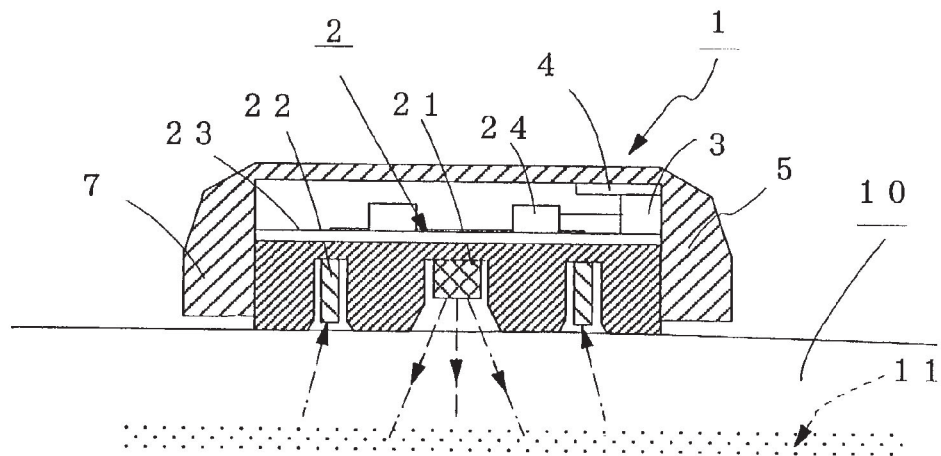


FIG. 5



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PULSE WAVE SENSOR AND PULSE RATE DETECTOR

BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention

[0002] The present invention relates to a pulse wave sensor for detecting the pulse wave of a subject from light reflected from a red corpuscle in the artery of a wrist of the subject by irradiating the artery of the wrist with light having a wavelength of an infrared range and to a pulse rate detector for detecting the pulse rate of the subject from the above pulse wave data.

[0003] 2. Description of the Prior Art

[0004] In recent years, along with shift to the aging society and westernized eating habits, an increase in the number of diseases caused by life habits, such as hyperpiesia, diabetes mellitus, heart diseases and cerebrovascular diseases of the brain is becoming a big social problem. As means of preventing these diseases or treating the diseases, a personal exercise cure such as walking is widely adopted. In this exercise cure, a pedometer or kinetic calorimeter is carried to know the quantity of motion. There has recently been proposed a method of estimating a burden on the heart of a person who takes exercise by real-time measuring his/her heart rate at the time of exercise.

[0005] For the measurement of the above heart rate, an optical pulse wave sensor for detecting the pulse wave of a subject from reflected light or transmitted light by irradiating the site of a blood vessel with light having an infrared or near infrared range is widely used. Stated more specifically, a pulse wave sensor which comprises a pair of an LED (light emitting diode) and a phototransistor (photodetector) is attached to a finger or ear to measure the heart rate by calculating the cycle (frequency) of pulse waves from the waveform of reflected light or transmitted light detected by the above photodetector.

[0006] However, although the conventional pulse wave sensor to be attached to the finger or ear is small in size, a signal from the sensor is weak because it detects the motion of a red corpuscle in the capillary and is easily affected by noise caused by the shaking of the body of the subject. Also, as some pressure is applied to the measurement site at the time of detection, the subject cannot carry the detector for a long time when walking or the like.

[0007] Meanwhile, since a strong signal is obtained when the motion of a red corpuscle in the artery is detected, a detector to be attached to a wrist or arm is conceivable. As understood when the pulse of the wrist is actually taken, it is difficult to attach the sensor to a predetermined position. When the attachment position is dislocated, no output can be obtained, thereby making it difficult to implement the detector.

SUMMARY OF THE INVENTION

[0008] It is an object of the present invention which has been made in view of the above problem to provide a pulse wave sensor which is easily attached and is capable of detecting a pulse wave accurately and a pulse rate detector comprising this pulse wave sensor.

[0009] According to a first aspect of the present invention, there is provided a pulse wave sensor for detecting a pulse wave by detecting light output from a light emitting diode and reflected from the artery of a wrist of a subject, the sensor comprising at least three photodetectors disposed around the light emitting diode and not linearly. Even when the attachment position of the sensor is dislocated, a pulse wave can be detected accurately.

[0010] According to a second aspect of the present invention, there is provided a pulse sensor, wherein a near infrared LED which is a general-purpose product is used as the light emitting diode. This makes it possible to produce an inexpensive sensor.

[0011] According to a third aspect of the present invention, there is provided a pulse sensor, wherein the photodetectors are disposed at an equal distance from the light emitting diode.

[0012] According to a fourth aspect of the present invention, there is provided a pulse sensor, wherein cavities are formed in a contact face between a holder for holding the light emitting diode and the photodetectors and the wrist, the light emitting face of the light emitting diode and the light receiving faces of the photodetectors are disposed at respective predetermined distances from the contact face, and the sectional forms of the cavities are tapered such that their widths increase toward the contact face. Since this makes it possible to expand the light emitting area and the light receiving area, a pulse wave can be easily detected even when the attachment position of the sensor is dislocated.

[0013] According to a fifth aspect of the present invention, there is provided a pulse sensor, wherein a transparent plate-like member is provided on a portion including at least the light emitting face and the light receiving faces of the contact face. This makes it possible to improve adhesion between the sensor and the wrist and thereby further improve the detection efficiency of pulse waves.

[0014] According to a sixth aspect of the present invention, there is provided a pulse rate detector comprising the pulse wave sensor of claim 1 and means of computing the pulse rate of a subject based on the output of the pulse wave sensor.

[0015] According to a seventh aspect of the present invention, there is provided a pulse rate detector which comprises a transmitter for transmitting the measured pulse rate data to a display for displaying the pulse rate data and a device for computing the amount of motion load from the pulse rate.

[0016] The above and other objects, advantages and features of the present invention will become apparent from the following description when taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIGS. 1 are schematic diagrams of a pulse rate detector according to an embodiment of the present invention;

[0018] FIG. 2 is a diagram showing that the pulse rate detector is attached.

[0019] FIG. 3 is a schematic diagram of a pulse wave which is the output of a photodetector;

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[0020] FIGS. 4 are diagrams showing other arrangements of a light emitting diode and photodetectors according to the present invention; and

[0021] FIG. 5 is a diagram showing a pulse rate detector according to another embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0022] Preferred embodiments of the present invention will be described hereinbelow with reference to the accompanying drawings.

[0023] FIGS. 1(a) and 1(b) are schematic diagrams of a pulse rate detector according to an embodiment of the present invention. FIG. 1(a) is a plan view and FIG. 1(b) is a sectional view of the pulse rate detector when it is attached. In these figures, reference numeral 2 denotes a pulse wave sensor which comprises an LED 21 (to be referred to as "light emitting diode" hereinafter) for emitting light having a wavelength of a near infrared range, four phototransistors 22 (to be referred to as "photodetectors" hereinafter) disposed around the light emitting diode 21 symmetrically on a circle concentric to the light emitting diode 21, a holder 23 for storing the above light emitting diode 21 and the photodetectors 22, and a drive detection circuit 24 for detecting a pulse wave by amplifying the outputs of the photodetectors 22, 3 is an arithmetic circuit for computing a pulse rate from the detected pulse wave data, 4 a transmitter for transmitting the above pulse rate data to an unshown display, 5 an outer casing for storing the above pulse wave sensor 2, the arithmetic circuit 3 and the transmitter 4, 6 an acrylic transparent plate mounted to the detection face 23a of the holder 23 to be described hereinafter, and 7 an attachment belt attached to the above outer casing.

[0024] The above light emitting diode 21 and the above photodetectors 22 are stored in cavities 23b and 23c formed in the detection face 23a which is a contact side between the holder 23 and a wrist 10, respectively, at positions where the light emitting face 21s of the light emitting diode 21 and the light receiving faces 22s of the photodetectors 22 are set back from the above detection face 23a. In this embodiment, to expand the light emitting area of the light emitting diode 21 and the light receiving areas of the photodetectors 22, the sectional forms of the above cavities 23b and 23c are tapered such that their widths increase toward the contact face.

[0025] A description is subsequently given of the method of measuring a pulse rate.

[0026] As shown in FIG. 2, a subject carries the above pulse rate detector 1 on the inner side of his/her wrist 10 with a belt in such a manner that the light emitting face 21s of the light emitting diode 21 faces down (on the wrist 10 side). As shown in FIG. 1(b), the above belt 7 is fastened such that the acrylic transparent plate 6 becomes close to the artery 11 of the wrist 10. Thereby, adhesion between the wrist 10 and the pulse rate detector 1 is improved. When the pulse rate detector 1 is attached to the wrist 10 with the belt 7, pulse wave data can be detected at the same pressure as that for attaching a wrist watch with a belt. Therefore, the wrist 10 is not pressed hard, thereby making it possible to carry it for a long time.

[0027] Near infrared radiation output toward the wrist 10 from the light emitting diode 21 is reflected by a red

corpuscle running through the artery 11 of the wrist 10 and this reflected light is detected by the plurality of photodetectors 22 so as to detect a pulse wave (see FIG. 1(b)). Since four photodetectors 22 are disposed around the light emitting diode 21 on a circle concentric to the light emitting diode 21 in this embodiment, even when the attachment position of the pulse rate detector 1 is dislocated, one of the photodetectors 22 is located near the artery 11, thereby making it possible to detect a pulse wave accurately. If the plurality of photodetectors 22 are disposed linearly, all of the photodetectors 22 may be far from the artery 11. Therefore, it is desired that the photodetectors 22 should not be disposed linearly.

[0028] FIG. 3 schematically shows the waveform of a pulse wave which is the output of the above photodetector 22. The detected pulse wave data is amplified by the drive detection circuit 24 and the amplified pulse wave data is transmitted to the arithmetic circuit 3. The arithmetic circuit 3 has a threshold value and computes the number of outputs above the threshold value per unit time so as to calculate a pulse rate and the transmitter 4 transmits the pulse rate to a display for displaying the above pulse rate data and a device for computing the amount of motion load. Since the output of the above photodetector 22 is generally low, after the output is amplified, the amplified output is converted into a digital signal for the computation of a pulse rate in this embodiment.

[0029] According to this embodiment, the pulse wave of the wrist 10 of the subject is detected by the pulse wave sensor 2 which comprises the light emitting diode 21 for emitting light having a wavelength of a near infrared range and four photodetectors 22 disposed around the light emitting diode 21 symmetrically on a circle concentric to the light emitting diode 21, and a pulse rate is computed from the pulse wave data by the arithmetic circuit 3. Therefore, even when the attachment position of the pulse rate detector 1 is dislocated, a pulse wave can be detected accurately.

[0030] Since the acrylic transparent plate 6 is provided on the detection face 23a of the holder 23, adhesion between the pulse rate detector 1 and the wrist 10 can be improved, thereby further improving the detection efficiency of a pulse wave.

[0031] In this embodiment, the pulse rate detector 1 is attached with the same pressure as that for attaching a timepiece to the wrist with a belt. Therefore, the subject can carry the pulse rate detector 1 for a long time without pressing his/her wrist excessively.

[0032] In the above embodiment, four photodetectors which are disposed symmetrically are used to detect the pulse wave of the wrist 10. The arrangement of the light emitting diode 21 and the photodetectors 22 is not limited to this. For example, to further improve detection efficiency, as shown in FIG. 4(a), the number of the photodetectors 22 may be increased. Alternatively, to reduce the size of the pulse rate detector 1, as shown in FIG. 4(b), the number of photodetectors may be reduced. In either case, it is desired that the photodetectors 22 should be disposed around the light emitting diode 21 on a circle concentric to the light emitting diode 21 to detect a pulse wave accurately even when the attachment position of the pulse rate detector 1 is dislocated.

[0033] In the above embodiment, a plurality of photodetectors 22 are provided for one light emitting diode 21. The

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same effect can be obtained when the number of photodetectors **22** is **1** and a plurality of light emitting diodes **21** are disposed around the photodetector **22**. In this case, the size and power consumption of the pulse wave sensor **2** become larger than this embodiment.

[0034] In the above embodiment, the acrylic transparent plate **6** is provided on the detection face **23a** of the holder **23** to improve adhesion to the wrist **10**. Even when the detection face **23a** is projected from the outer casing **5** as shown in **FIG. 5**, adhesion can be improved.

[0035] In the above embodiment, the pulse rate data is transmitted to the display or the device for computing the amount of motion load. When not only a pulse rate but also pulse wave data (waveform itself) are transmitted, the pulse rate detector **1** of the present invention can be coupled to devices making use of bio signals.

[0036] As described above, according to the present invention, since a pulse wave sensor is constituted such that light output from a light emitting diode and reflected from the artery of the wrist of a subject is detected by at least three photodetectors disposed around the light emitting diode and not linearly to detect a pulse wave, even when the attachment position of the sensor is dislocated, the pulse wave can be detected accurately. Using this sensor, a pulse rate detector which is easily attached and has a stable output can be constructed.

What is claimed is:

1. A pulse wave sensor for detecting a pulse wave by detecting light output from a light emitting diode and reflected from the artery of a wrist of a subject, the sensor comprising at least three photodetectors disposed around the light emitting diode.

2. The pulse wave sensor of claim 1, wherein a near infrared LED is used as the light emitting diode.

3. The pulse wave sensor of claim 1, wherein the photodetectors are disposed at an equal distance from the light emitting diode.

4. The pulse sensor of claim 1, wherein cavities are formed in a contact face between a holder for holding the light emitting diode and the photodetectors and the wrist, the light emitting face of the light emitting diode and the light receiving faces of the photodetectors are disposed at respective predetermined distances from the contact face, and the sectional forms of the cavities are tapered such that their widths increase toward the contact face.

5. The pulse wave sensor of claim 1, wherein a transparent plate-like member is provided on a portion including at least the light emitting face and the light receiving faces of the contact face.

6. A pulse rate detector comprising the pulse wave sensor of claim 1 and means of computing the pulse rate of a subject based on the output of the pulse wave sensor.

7. The pulse rate detector of claim 6 which comprises a transmitter for transmitting the measured pulse rate data.

* * * * *

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(71) 出願人 000004260
 株式会社デンソー
 愛知県刈谷市昭和町1丁目1番地
 (74) 代理人 100082500
 弁理士 足立 勉
 (72) 発明者 井野川 和也
 愛知県刈谷市昭和町1丁目1番地 株式会
 社デンソー内
 (72) 発明者 射延 恭二
 愛知県刈谷市昭和町1丁目1番地 株式会
 社デンソー内
 (72) 発明者 西井 克昌
 愛知県刈谷市昭和町1丁目1番地 株式会
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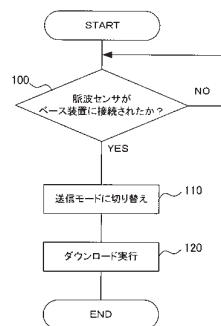
(54) 【発明の名称】 光学式生体センサ、ベース装置、生体情報収集システム、及びセンサ通信方法

(57) 【要約】

【課題】 故障が少なく簡易な構成で情報の送信や受信を行うことができる光学式生体センサ、ベース装置、生体情報収集システム、及びセンサ通信方法を提供すること。

【解決手段】 S100では、脈波センサ1とベース装置17とが接続されたか否かを判定する。つまり、S側接触検知端子19とB側接触検知端子39とが接触し、それによって、B側接触検知端子39からS側接触検知端子19に接触検知信号が入力されたか否かを判定する。S110では、CPU61の制御モードを、測定モードから送信モードに切り換える。続くS120では、送信モードにて、メモリに記憶された脈波等のデータをベース装置17側に送信する。即ち、データのダウンロードを実行する。つまり、脈波センサ1がベース装置17に装着されると、脈波センサ1からベース装置17に自動的に脈波等の情報が送信される。

【選択図】 図8



【特許請求の範囲】

【請求項 1】

生体に対して光を照射するセンサ側発光手段と、
前記センサ側発光手段から照射され前記生体にて反射する反射光を受光するセンサ側受光手段と、
前記センサ側受光手段にて受光した反射光に基づいて前記生体の状態を検出する生体状態検出手段と、
を有するセンサ側光学装置部を備えた光学式生体センサにおいて、
前記生体状態検出手段にて検出した前記生体の情報を、前記センサ側発光手段を用いて、前記光学式生体センサの送信相手のベース装置に送信することを特徴とする光学式生体センサ。

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【請求項 2】

前記光学式生体センサは、前記生体状態検出手段によって生体の状態を検出する測定モードと、前記生体の情報を前記ベース装置に送信する送信モードと、を有することを特徴とする請求項 1 に記載の光学式生体センサ。

【請求項 3】

前記ベース装置に装着されたことを検知するセンサ側接触検知部を備えたことを特徴とする請求項 1 又は 2 に記載の光学式生体センサ。

【請求項 4】

前記ベース装置に装着されたことを検知した場合には、前記送信モードに設定することを特徴とする請求項 3 に記載の光学式生体センサ。

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【請求項 5】

前記測定モードと前記送信モードとに切り換えるモード切換スイッチを備えたことを特徴とする請求項 2 ～ 4 のいずれかに記載の光学式生体センサ。

【請求項 6】

前記ベース装置の電力供給構成により充電される充電部を備えたことを特徴とする請求項 1 ～ 5 のいずれかに記載の光学式生体センサ。

【請求項 7】

前記センサ側発光手段を、2 個以上備えたことを特徴とする請求項 1 ～ 6 のいずれかに記載の光学式生体センサ。

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【請求項 8】

前記センサ側発光手段の表面側にレンズを配置したことを特徴とする請求項 1 ～ 7 のいずれかに記載の発光式生体センサ。

【請求項 9】

前記センサ側発光手段の表面側に透光性のカバーを配置したことを特徴とする請求項 1 ～ 7 のいずれかに記載の発光式生体センサ。

【請求項 10】

前記カバーが可視光カット機能を有することを特徴とする請求項 9 に記載の発光式生体センサ。

【請求項 11】

前記請求項 1 ～ 10 のいずれかに記載の光学式生体センサから前記生体の情報が送信されるベース装置であって、

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前記センサ側発光手段によって送信された前記生体の情報を受信するベース側受光手段を有するベース側光学装置部を備えたことを特徴とするベース装置。

【請求項 12】

前記ベース側光学装置部には、更に、前記センサ側光学装置部に対して信号を送信するベース側発光手段を備えたことを特徴とする請求項 11 に記載のベース装置。

【請求項 13】

前記ベース側発光手段を用いて、前記センサ側受光手段に対して、前記センサ側受光手段からの前記生体の情報の送信を指令する指令信号を送信することを特徴とする請求項 1

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2に記載のベース装置。

【請求項14】

前記ベース装置は、前記光学式生体センサが接触した状態で装着される装着構造を備えたことを特徴とする請求項11～13のいずれかに記載のベース装置。

【請求項15】

前記光学式生体センサを前記ベース装置に装着した場合に、前記光学式生体センサを傾斜させる構成としたことを特徴とする請求項14に記載のベース装置。

【請求項16】

前記ベース装置に対して前記光学式生体センサを水平に装着する構成としたことを特徴とする請求項14に記載のベース装置。

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【請求項17】

前記光学式生体センサが装着された場合に、前記光学式生体センサに検知信号を送信するベース側接触検知部を備えたことを特徴とする請求項11～16のいずれかに記載のベース装置。

【請求項18】

前記光学式生体センサの充電部を充電するための電力供給構成を有することを特徴とする請求項11～17のいずれかに記載のベース装置。

【請求項19】

前記ベース側受光手段を、2個以上備えたことを特徴とする請求項11～18のいずれかに記載のベース装置。

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【請求項20】

前記ベース装置は、前記光学式生体センサを嵌め込む凹部を備えたことを特徴とする請求項11～19のいずれかに記載のベース装置。

【請求項21】

前記凹部は、前記光学式生体センサの底部に対応した底部側凹部及び／又はセンサ側光学装置部側に対応した側面側凹部であることを特徴とする請求項20に記載のベース装置。

【請求項22】

前記凹部は、前記光学式生体センサの装着方向に沿った溝であることを特徴とする請求項20又は21に記載のベース装置。

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【請求項23】

前記側面側凹部の溝は、中央部が更に凹状となっていることを特徴とする請求項21又は22に記載の生体情報収集システム。

【請求項24】

前記底部側凹部の深さは、バンドを備えた前記光学式生体センサを嵌めたときに、前記バンドが邪魔にならない深さに設定されていることを特徴とする請求項21又は22に記載のベース装置。

【請求項25】

前記ベース装置は、前記光学式生体センサを載置する基台部と、該基台部から立設される立設部とを備えることを特徴とする請求項11～24のいずれかに記載のベース装置。

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【請求項26】

前記基台部と前記立設部との間に段差を有することを特徴とする請求項25に記載のベース装置。

【請求項27】

バンドを備えた前記光学式生体センサに対して、そのバンドを前記立設部に外嵌可能な構成としたことを特徴とする請求項25又は26に記載のベース装置。

【請求項28】

前記立設部の側面に、曲面を有することを特徴とする請求項25～27のいずれかに記載のベース装置。

【請求項29】

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前記ベース側発光手段の表面側にレンズを配置したことを特徴とする請求項 11～28 のいずれかに記載のベース装置。

【請求項 30】

前記ベース側発光手段の表面側に透光性のカバーを配置したことを特徴とする請求項 11～28 のいずれかに記載のベース装置。

【請求項 31】

前記カバーが可視光カット機能を有することを特徴とする請求項 30 に記載のベース装置。

【請求項 32】

前記請求項 1～10 のいずれかに記載の光学式生体センサと、前記請求項 11～31 のいずれかに記載のベース装置と、を備えたことを特徴とする生体情報収集システム。 10

【請求項 33】

前記センサ側発光手段を用いて送信された前記生体の情報を、前記ベース側受光手段によって受信することを特徴とする請求項 32 に記載の生体情報収集システム。

【請求項 34】

前記ベース側発光手段を用いて送信された所定の指令信号を、前記センサ側受光手段にて受信することを特徴とする請求項 32 又は 33 に記載の生体情報収集システム。

【請求項 35】

前記ベース側発光手段によって前記指令信号が送信された場合には、前記指令信号に基づいて、前記光学式生体センサを前記送信モードに設定することを特徴とする請求項 34 に記載の生体情報収集システム。 20

【請求項 36】

前記光学式生体センサを前記ベース装置に装着した場合に、前記センサ側光装置部と前記ベース側光装置部とが、互いに相対する位置に配置される構成としたことを特徴とする請求項 32～35 のいずれかに記載の生体情報収集システム。

【請求項 37】

前記光学式生体センサを前記ベース装置に装着した場合に、発光手段側と受光手段側との距離及び位置が一定となるように、前記光学式生体センサと前記ベース装置とを嵌め込む構造としたことを特徴とする請求項 32～36 のいずれかに記載の生体情報収集システム。 30

【請求項 38】

前記センサ側発光手段として赤外 LED を用いる場合には、前記ベース側受光手段の表面側に可視光カット部材を配置することを特徴とする請求項 32～37 のいずれかに記載の生体情報収集システム。

【請求項 39】

前記ベース側光学装置部と前記センサ側光学装置部とにレンズが配置されている場合に、互いのレンズの凹凸が嵌合する構成を有することを特徴とする請求項 32～38 のいずれかに記載の生体情報収集システム。

【請求項 40】

前記ベース側光学装置部と前記センサ側光学装置部とに透光性のカバーが配置されている場合に、互いのカバーの凹凸が嵌合する構成を有することを特徴とする請求項 32～38 のいずれかに記載の生体情報収集システム。 40

【請求項 41】

前記ベース装置の端子と前記光学式生体センサの端子とが、機械的に接触する構成を有することを特徴とする請求項 32～40 のいずれかに記載の生体情報収集システム。

【請求項 42】

互いに接触する前記端子の形状により、前記光学式生体センサを装着する向きが規定される構成を有することを特徴とする請求項 41 に記載の生体情報収集システム。

【請求項 43】

前記ベース装置と前記光学式生体センサとの間の信号の送受信を、電磁気を用いて行う 50

構成を備えたことを特徴とする請求項 3 2 ～ 4 2 のいずれかに記載の生体情報収集システム。

【請求項 4 4】

前記ベース装置から前記光学式生体センサに対して、電磁気を用いて電力を供給する構成を備えたことを特徴とする請求項 3 2 ～ 4 3 のいずれかに記載の生体情報収集システム。

【請求項 4 5】

前記センサ側光学装置部に 2 個以上のセンサ側発光手段が配置されている場合に、前記ベース側光学装置部に前記各センサ側発光手段に対応してそれぞれベース側受光手段を備えたことを特徴とする請求項 3 2 ～ 4 4 のいずれかに記載の生体情報収集システム。

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【請求項 4 6】

前記センサ側光学装置部及び前記ベース側光学装置部に、複数対の前記発光手段及び受光手段を備え、複数対の前記発光手段及び受光手段を用いて、前記生体の情報の送信を行うことを特徴とする請求項 4 5 に記載の生体情報収集システム。

【請求項 4 7】

前記センサ側光学装置部及び前記ベース側光学装置部に、複数対の前記発光手段及び受光手段を備え、ある対の前記発光手段及び受光手段を用いて、前記生体の情報の送信を行うとともに、他の対の前記発光手段及び受光手段を用いて、前記送信される生体の情報のチェックを行うためのチェック情報を送信することを特徴とする請求項 4 5 に記載の生体情報収集システム。

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【請求項 4 8】

前記請求項 1 ～ 1 0 のいずれかに記載の光学式生体センサと前記請求項 1 1 ～ 3 1 のいずれかに記載のベース装置との間のセンサ通信方法であって、

前記センサ側発光手段を用いて、前記ベース側受光手段に対して、前記生体の情報を送信することを特徴とするセンサ通信方法。

【請求項 4 9】

前記光学式生体センサが前記ベース装置に装着された場合には、前記光学式生体センサから前記ベース装置に、前記生体の情報を送信することを特徴とする請求項 4 8 に記載のセンサ通信方法。

【請求項 5 0】

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前記ベース装置から前記光学式生体センサに対して、所定の指令信号が送信された場合に、前記光学式生体センサから前記ベース装置に、前記生体の情報を送信することを特徴とする請求項 4 8 又は 4 9 に記載のセンサ通信方法。

【請求項 5 1】

前記光学式生体センサが前記ベース装置に装着された場合には、前記光学式生体センサを待機モードに設定し、前記ベース装置から指令信号を受信した場合には、前記光学式生体センサから前記ベース装置に、前記生体の情報を送信することを特徴とする請求項 5 0 に記載のセンサ通信方法。

【請求項 5 2】

前記光学式生体センサがモード切換スイッチによって待機モードに設定されている場合に、前記光学式生体センサから前記ベース装置に前記指令信号を要求する要求信号を送信し、前記ベース装置から指令信号を受信した場合には、前記光学式生体センサから前記ベース装置に、前記生体の情報を送信することを特徴とする請求項 5 1 に記載のセンサ通信方法。

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【請求項 5 3】

前記光学式生体センサがモード切換スイッチによって待機モードに設定されている場合に、前記ベース装置から指令信号を受信した場合には、前記光学式生体センサから前記ベース装置に、前記生体の情報を送信することを特徴とする請求項 5 0 に記載のセンサ通信方法。

【発明の詳細な説明】

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【技術分野】

【0001】

本発明は、生体から脈波などの各種の情報を得ることができる光学式生体センサ、ベース装置、生体情報収集システム、及びセンサ通信方法に関するものである。

【背景技術】

【0002】

従来より、例えば医療現場などにおいて、患者等の状態を的確に把握するために、例えば光学式脈波センサが使用されていた。

この種の脈波センサでは、脈波を計測する際には、計測したデータをメモリに保存していた。そして、計測の終了後に、脈波センサと通信機能付きの充電器（基地局）とをケーブルに接続するとともに、基地局とパソコンとをケーブルで接続し、パソコンからの指令によって、脈波センサからデータをダウンロードする技術が知られている。

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【0003】

また、またこれとは別に、生体情報検出するセンサから、その情報を収集する基地局に対して、無線通信にてデータを送信する技術もあった（引用文献1～3参照）。

【特許文献1】特開平2003-275183号公報

【特許文献2】特開平2003-309485号公報

【特許文献3】特開平2000-270486号公報

【発明の開示】

【発明が解決しようとする課題】

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【0004】

しかしながら、上述した様に、脈波センサと基地局とをケーブルによって機械的に接続するシステムでは、破損や劣化によって接触不良が生じる恐れがあった。

また、データを無線で送信するシステムの場合には、生体情報の検出の回路等とは別に、専用の無線通信回路が必要になるという問題があった。

【0005】

本発明は、前記課題を解決するためになされたものであり、その目的は、故障が少なく簡易な構成で情報の送信や受信を行うことができる光学式生体センサ、ベース装置、生体情報収集システム、及びセンサ通信方法を提供することにある。

【課題を解決するための手段】

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【0006】

（1）請求項1の発明では、生体状態検出手段にて検出した生体の情報を、センサ側発光手段を用いて、光学式生体センサの送信相手であるベース装置に送信する。

つまり、光学式生体センサ（例えば脈波センサ）には、生体の情報（例えば脈波等）を検出するために、LED等のセンサ側発光手段を備えているので、このセンサ発光手段を用いて、生体の情報をベース装置に送信する。

【0007】

これにより、従来の様な無線通信回路を用いたり通信用のケーブルで接続することが不要となるので、故障が少なく簡易な構成で容易に生体の情報を送信することができる。

尚、送信される生体の情報としては、光学式生体センサに測定されてメモリに記憶された各種の情報、つまり、反射光から得られる各種の信号、例えば脈波（脈拍数、脈拍間隔）や体動などを示す信号や、その信号を解析したことにより得られる情報が考えられる。また、測定された生の測定データ（メモリに記憶されたデータ）を送信するようにしてもよい。

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【0008】

（2）請求項2の発明では、光学式生体センサは、生体状態検出手段によって生体の状態を検出する測定モードと、生体の情報をベース装置に送信する送信モードとを有するので、モードを切り換えることにより、各モードに対応した動作を行う。

【0009】

尚、ベース装置からの指令信号（送信を指令する信号）があるまでは、ベース装置に生

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体の情報を送信することを待機する待機モードを備えていてもよい。

(3) 請求項3の発明では、センサ側接触検知部により、光学式生体センサがベース装置に装着されたことを検知することができる。

【0010】

尚、このセンサ側接触検知部としては、ベース側の端子（ベース側接触検知部）と接触する端子が挙げられる。また、ベース側の端子と接触することなく、電磁気により検知する構成としてもよい。

【0011】

(4) 請求項4の発明では、ベース装置に装着されたことを検知した場合には、送信モードに設定する。これにより、光学式生体センサがベース装置に装着された場合には、自動的に生体の情報を送信することができる。

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【0012】

(5) 請求項5の発明では、測定モードと送信モードとに切り換えるモード切換スイッチを備えている。従って、このモード切換スイッチによって、モードを切り換えることができるので、所望のタイミングで、光学式生体センサに所望の処理を作動させることができる。

【0013】

(6) 請求項6の発明では、充電部を備えているので、ベース装置の電力供給構成により充電することができる。

尚、充電を行うために、光学式生体センサとベース装置とに互いに接触する端子を備えてもよいが、電磁気により電力を供給する構成としてもよい。

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【0014】

(7) 請求項7の発明では、センサ側発光手段として、2個以上の例えばLED等の発光手段を備えている。

従って、複数のセンサ側発光手段を用いて生体の情報を送信することにより、効率よく送信することができる。また、生体の情報を送信する手段と、チェックサムの様な情報のチェックを行う情報を送信する手段との様に、発光手段の役割を区別することができる。更に、例えば赤外LEDや緑LEDの様に、異なる種類のセンサ側発光手段を用いる場合には、各手段の特性に合わせた使用方法ができる。例えば、赤外LEDは体動の検出や情報の送信を行い、緑LEDは脈波の検出を行うように、役割を分けることができる。

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【0015】

(8) 請求項8の発明では、センサ側発光手段の表面側にレンズを配置している。

このレンズにより例えばLEDの集光性を高めることができ、また、例えばLEDやPDを保護することもできる。

【0016】

(9) 請求項9の発明では、センサ側発光手段の表面側に透光性のカバーを配置している。

このカバーにより例えばLEDやPDを保護することができる。尚、カバーの内側にレンズを配置してもよい。

【0017】

(10) 請求項10の発明では、カバーが可視光カット機能を有するので、可視光によるノイズをカットすることができる。

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(11) 請求項11の発明は、光学式生体センサから生体の情報が送信されるベース装置であり、このベース装置では、ベース側光学装置部のベース側受光手段によって、生体の情報を受信する。

【0018】

(12) 請求項12の発明では、ベース側発光手段によって、センサ側光学装置部（のセンサ側受光手段）に対して、各種の信号（例えば生体の情報送信を要求する指令信号等）を送信することができる。

【0019】

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(13) 請求項13の発明では、ベース側発光手段を用いて、センサ側受光手段に対して、センサ側受光手段からの生体の情報の送信を指令する指令信号を送信する。

(14) 請求項14の発明では、ベース装置は、光学式生体センサが接触した状態で装着される装着構造を備えている。従って、光学式生体センサをベース装置に装着することができる。

【0020】

(15) 請求項15の発明では、光学式生体センサは、ベース装置に傾斜（垂直方向に対して斜め）して装着される。従って、重力によって、センサ側光学装置部とベース側光学装置部とを近接して（又は接触して）配置することができる。

【0021】

(16) 請求項16の発明では、光学式生体センサは、ベース装置に対して水平に装着される。

(17) 請求項17の発明では、ベース装置にはベース側接触検知部を備えているので、光学式生体センサが装着された場合に、光学式生体センサのベース側接触検知部に対して、装着されたことを示す検知信号（例えば接触検知信号）を送信することができる。

【0022】

尚、ベース側接触検知部としては、直接に接触する端子、又は電磁気により検知信号を送信する検知部を採用できる。

(18) 請求項18の発明では、電力供給構成を有するので、この電力供給構成により光学式生体センサの充電部を充電することができる。

【0023】

尚、電力供給構成としては、直接に接触する端子、又は電磁気により充電を行う構成を採用できる。

(19) 請求項19の発明では、（センサ側発光手段に対応して）ベース側受光手段を、2個以上備えている。

【0024】

従って、複数のベース側受光手段を用いて、効率よく生体の情報を受信することができる。また、生体の情報を受信する手段と、チェックサム等の様な情報のチェックを行う情報を受信する手段との様に、役割を区別することができる。

【0025】

(20) 請求項20の発明では、ベース装置には、光学式生体センサが嵌め込まれる凹部を備えているので、光学式生体センサを簡単に装着することができる。

(21) 請求項21の発明は、凹部を例示したものである。底部側凹部には光学式生体センサの底部（装着する方向の先端側）が嵌め込まれ、側面側凹部には光学式生体センサのセンサ側光学装置部側が嵌め込まれる。

【0026】

(22) 請求項22の発明は、溝状の凹部を例示したものである。

(23) 請求項23の発明では、側面側凹部の溝は、中央部が更に凹状となっているので、この凹状部分に、センサ側光学装置部を配置することができる。

【0027】

(24) 請求項24の発明では、底部側凹部の深さは、光学式生体センサを嵌めたときに、バンドが邪魔にならない深さに設定されているので、光学式生体センサの装着を容易に且つ確実に行うことができる。これにより、送信も確実に行うことができる。

【0028】

(25) 請求項25の発明は、基台部と立設部とを備えたベース装置を例示したものである。

(26) 請求項26の発明は、基台部と立設部との間に段差を有するので、バンド付きの光学式生体センサの装着が容易である。

【0029】

(27) 請求項27の発明では、光学式生体センサのバンドを立設部に外嵌することが

できる。

(28) 請求項28の発明では、立設部の側面に曲面を有するので、丸くなったバンドを簡単にかけることができる。

【0030】

(29) 請求項29の発明では、ベース側発光手段の表面側にレンズを備えている。

このレンズにより例えばLEDの集光性を高めることができ、また、例えばLEDやPDを保護することもできる。

【0031】

(30) 請求項30の発明では、ベース側発光手段の表面側に透光性のカバーを備えている。

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このカバーにより例えばLEDやPDを保護することができる。尚、カバーの内側にレンズを配置してもよい。

【0032】

(31) 請求項31の発明では、カバーに可視光カット機能を有する。

(32) 請求項32の発明では、生体情報収集システムは、光学式生体センサとベース装置とを備えている。

【0033】

(33) 請求項33の発明では、センサ側発光手段を用いて送信された生体の情報を、ベース側受光手段によって受信することができる。

(34) 請求項34の発明では、ベース側発光手段を用いて送信された所定の指令信号(例えば光学式生体センサから生体の情報を送信させる信号)を、センサ側受光手段にて受信することができる。

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【0034】

(35) 請求項35の発明では、ベース側発光手段によって指令信号が送信された場合には、指令信号に基づいて、光学式生体センサを送信モードに設定する。これにより、光学式生体センサからベース装置に対して、生体の情報を送信することが可能になる。

【0035】

(36) 請求項36の発明では、光学式生体センサがベース装置に装着された場合に、センサ側光装置部とベース側光装置部とは、互いに相対する位置に配置されるので、光学的手段によって、好適に情報の送受信を行うことができる。

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【0036】

(37) 請求項37の発明では、光学式生体センサをベース装置に装着した場合に、発光手段側と受光手段側との距離及び位置が一定となるように、光学式生体センサとベース装置とを嵌め込む構造としている。

【0037】

これにより、ベース装置に光学式生体センサを嵌め込んだ場合には、発光手段側と受光手段側との距離及び位置が常に一定となるので、精度良く情報の送受信を行うことができる。

【0038】

尚、発光手段と受光手段としては、センサ側発光手段とベース側受光手段、ベース側発光手段とセンサ側受光手段が挙げられる。

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(38) 請求項38の発明では、センサ側発光手段として赤外LEDを用いる場合には、ベース側受光手段の表面側に可視光カット部材を配置するので、可視光によるノイズをカットすることができる。

【0039】

(39) 請求項39の発明では、ベース側光学装置部とセンサ側光学装置部とにレンズが配置されている場合には、互いのレンズの凹凸が嵌合する構成であるので、位置ずれがなく、光学的手段によって、好適に情報の送受信を行うことができる。

【0040】

(40) 請求項40の発明では、ベース側光学装置部とセンサ側光学装置部とに透光性

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のカバーが配置されている場合には、互いのカバーの凹凸が嵌合する構成であるので、位置ずれがなく、光学的な手段によって、好適に情報の送受信を行うことができる。

【0041】

(41) 請求項41の発明では、ベース装置の端子と光学式生体センサの端子とが、機械的に接触する構成である。

(42) 請求項42の発明では、互いに接触する端子の形状により、光学式生体センサを装着する向きが規定される構成であるので、装着する向きを間違えることがない。

【0042】

(43) 請求項43の発明では、ベース装置と光学式生体センサとの間の信号の送受信を、電磁気を用いて行う構成である。

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(44) 請求項44の発明では、ベース装置から光学式生体センサに対して、電磁気を用いて電力を供給する構成である。

【0043】

(45) 請求項45の発明では、センサ側光学装置部に2個以上のセンサ側発光手段が配置されている場合に、ベース側光学装置部には、各センサ側発光手段に対応してそれぞれベース側受光手段が配置されている。

【0044】

従って、複数のセンサ側発光手段を用いて生体の情報を送信することにより、効率よく送信することができる。また、生体の情報を送信する手段と、チェックサム等の様な情報のチェックを行う情報を送信する手段との様に、役割を区別することができる。更に、例えば赤外LEDや緑LEDの様に、異なる種類のセンサ側発光手段を用いる場合には、各手段の特性に合わせた使用方法ができる。

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【0045】

(46) 請求項46の発明では、センサ側光学装置部及びベース側光学装置部に、複数対の発光手段及び受光手段を備え、複数対の発光手段及び受光手段を用いて、生体の情報の送信を行う。

【0046】

尚、複数対の発光手段及び受光手段としては、例えば光学式生体センサに第1発光手段を備えるとともに、それに対応して、ベース装置に第1受光手段を備え、更に、光学式生体センサに第2発光手段を備えるとともに、それに対応して、ベース装置に第2受光手段を備えた場合が挙げられる。

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【0047】

(47) 請求項47の発明では、センサ側光学装置部及びベース側光学装置部に、複数対の発光手段及び受光手段を備え、複数対の発光手段及び受光手段を区別して用いて、生体の情報の送信と、送信される生体の情報のチェックを行うためのチェック情報を送信する。

【0048】

尚、複数対の発光手段及び受光手段としては、例えば光学式生体センサに（生体の情報を送信するための）第1発光手段を備えるとともに、それに対応して、ベース装置に第1受光手段を備え、更に、光学式生体センサに（チェックサム等の情報を送信するための）第2発光手段を備えるとともに、それに対応して、ベース装置に第2受光手段を備えた場合が挙げられる。

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【0049】

(48) 請求項48の発明は、光学式生体センサとベース装置との間のセンサ通信方法であって、センサ側発光手段を用いて、ベース側受光手段に対して、生体の情報を送信する。

【0050】

(49) 請求項49の発明では、光学式生体センサがベース装置に装着された場合には、光学式生体センサからベース装置に、生体の情報を送信する。

(50) 請求項50の発明では、ベース装置から光学式生体センサに対して、所定の指

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令信号（生体の情報の送信を要求する信号）が送信された場合に、光学式生体センサからベース装置に、生体の情報を送信する。

【0051】

（51）請求項51の発明では、光学式生体センサがベース装置に装着された場合には、光学式生体センサを待機モードに設定し、ベース装置から指令信号を受信した場合には、光学式生体センサからベース装置に、生体の情報を送信する。

【0052】

（52）請求項52の発明では、光学式生体センサがモード切換スイッチによって待機モードに設定されている場合に、光学式生体センサからベース装置に指令信号を要求する要求信号を送信し、ベース装置から指令信号を受信した場合には、光学式生体センサからベース装置に、生体の情報を送信する。

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【0053】

（53）請求項53の発明では、光学式生体センサがモード切換スイッチによって待機モードに設定されている場合に、ベース装置から指令信号を受信した場合には、光学式生体センサからベース装置に、生体の情報を送信する。

【発明を実施するための最良の形態】

【0054】

以下に本発明の最良の実施形態（実施例）を、図面と共に説明する。

【実施例1】

【0055】

ここでは、被験者の脈波等の生体情報を検出し、この情報をベース装置に対して送信することができる光学式生体センサ、ベース装置、生体情報収集システム、及びセンサ通信方法について説明する。

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【0056】

a) まず、本実施例の光学式生体センサについて説明する。

図1に示す様に、光学式生体センサは、人体の例えば指や手首等に取り付けて、脈波等を検出できる脈波センサ1である。

【0057】

この脈波センサ1は、周知の光学式反射型センサであり、箱状のセンサ本体3と、（センサ本体3に接続され）伸縮性を有する環状のリストバンド5とを備えている。

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センサ本体3の表側の表面には、表示部7と操作スイッチ9とを備えており、裏側の表面には、脈波等を光学的に検出するセンサ側（S側）光学装置部11を備えている

また、センサ本体3の左右方向（リストバンド5と垂直の方向）の一方の側面には、センサ本体3を充電するための一対のS側充電用端子13、15と、センサ本体3がベース装置17（図3参照）に装着されたことを検出するS側接触検知端子19とを備えている。尚、前記操作スイッチ9は、電源ONと電源OFFと脈波の測定開始の3位置に切り換えられるスイッチである。

【0058】

図2に示す様に、脈波センサ1は、一対の発光素子、即ち緑光の発光ダイオード（S側緑LED）21と、赤外光の発光ダイオード（S側赤外LED）23と、その反射光を受光する1個のフォトダイオード（S側PD）25と、S側レンズ27とを備えている。

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【0059】

このうち、S側緑LED21は、基本性能として、その人体に対する反射光から（即ち毛細動脈にあるヘモグロビンの量の変化から）脈波を検出するためのものであり、S側赤外LED23は、その反射光の変化から、体動を検出するためのものである。

【0060】

b) 次に、本実施例のベース装置17について説明する。

図3に模式的に示す様に、ベース装置17は、脈波センサ1が装着して使用される通信機能付き充電器であり、脈波センサ1が載置される基台部31と、基台部31から斜めに立設される板状の立設部33とを備えている。

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【0061】

ベース装置17の基台部31の上面側には、図4に示す様に、脈波センサ1の充電用端子13、15及びS側接触検知端子19に対応して、脈波センサ1に対する充電を行うためのベース側（B側）充電用端子35、37と、S側接触検知端子19に接触するB側接触検知端子39を備えている。尚、B側充電用端子35、37及びB側接触検知端子39は、バネ（図示せず）により上方に付勢され上下に移動可能である。

【0062】

前記図3に戻り、脈波センサ1のS側光学装置部11に対向して、ほぼ同様なB側光学装置部41が配置されている。つまり、B側光学装置部41は、B側赤外LED43、B側PD45、B側レンズ47を備えており、B側PD45はS側赤外LED23と対向して配置されるとともに、B側赤外LED43はS側PD25と対向するように配置されている。

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【0063】

また、図5（b）に示す様に、ベース装置17の基台部31には、脈波センサ1の底部形状に対応して、脈波センサ1が嵌合する溝状の底部側嵌合凹部51が設けられているので、脈波センサ1を装着方向に移動させて、ずれ無く底部側嵌合凹部51に嵌め込むことができる。

【0064】

更に、図5（a）に示す様に、立設部33の脈波センサ1の装着側（同図下方）には、脈波センサ1の外形形状に合わせて、側面側嵌合凹部53が設けられており、この側面側嵌合凹部53の中央部、即ちS側光学装置部11及びB側光学装置部41に対応する位置には中央凹部55が設けられている。

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【0065】

また、図6に示す様に、脈波センサ1のリストバンド5は、ベース装置17の立設部33に外嵌するように配置される。また、立設部33の裏側（図6（b）の上方）に支柱57を設ける場合には、立設部33及び支柱57に外嵌するようにリストバンド5を配置する。尚、前記底部側嵌合凹部51の深さは、脈波センサ1を立設部33等に外嵌した場合に、リストバンド5が基台部31の表面に当たらない深さに設定されている。

【0066】

c) 次に、前記脈波センサ1及びベース装置17からなる生体情報収集システムの電気的構成について説明する。

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本実施例の生体情報収集システムは、ベース装置17と、ベース装置17に装着（着座）される脈波センサ1とから構成されている。

そして、脈波センサ1の装着によって、S側光学装置部11とB側光学装置部41とが近接して対向し、それによって、S側赤外LED23とB側PD45とが対向するとともに、S側PS25とB側赤外LED43とが対向する。また、S側接触検知端子19とB側接触検知端子39とが接触する。尚、S側充電用端子13、15とB側充電用端子35、37とも接触する。

【0067】

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この生体情報収集システムでは、脈波センサ1は、S側光学装置部11により、脈波等の検出を行うとともに、脈波等の情報をベース装置17に出力し、一方、ベース装置17は、B側光学装置部41により、脈波センサ1から送信された情報を受信する。尚、ベース装置17はパソコン59に接続されており、脈波センサ1から送信された情報は、ベース装置17を介してパソコン59にダウンロードされる。以下、詳しく説明する。

【0068】

・前記脈波センサ1は、脈波センサ1を制御するCPU61と、検出した脈波等の情報を記憶するメモリ63と、前記S側接触検知端子19と、前記S側赤外LED23と、前記S側緑LED21と、S側赤外LED23及びS側緑LED21を駆動するS側LEDドライブ回路65と、前記S側PD25と、S側PD25から入力した信号を増幅するS

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側増幅回路67と、S側増幅信号67から入力したアナログ信号を基準電圧と比較してデジタル信号を生成するS側比較回路69と、基準電圧を生成するS側基準電圧回路71とを備えている。

【0069】

そして、前記CPU61は、測定モードにて、脈波や体動を検出を行うための制御を行う。即ち、S側ドライブ回路65を駆動して、S側赤外LED23及びS側緑LED21を制御し、S側PD25にて受光した信号から脈波や体動を検出するための処理を行い、その解析データを一旦メモリ63に記憶する。尚、S側比較回路69にて変換されたデジタル信号はCPU61に入力される。

【0070】

また、CPU61は、送信モードにて、脈波等の情報をベース装置17に送信するための制御を行う。即ち、S側ドライブ回路65を駆動して、S側赤外LED23を制御し、メモリ63に記憶した情報を光学的な信号として、ベース装置17側に送信する。

【0071】

・前記ベース装置17は、S側接触検知端子19に接触して信号（接触したことを報知する接触検知信号）を送信するB側接触検知端子39と、B側接触検知端子39に送信する接触検知信号を生成する接触検知信号回路73と、前記B側PD45と、B側PD45から入力した信号を増幅するB側増幅回路75と、B側増幅信号75から入力したアナログ信号を基準電圧と比較してデジタル信号を生成するB側比較回路77と、基準電圧を生成するB側基準電圧回路79と、前記B側赤外LED43と、B側赤外LED43を駆動するB側LEDドライブ回路81と、B側LEDドライブ回路81の制御信号を出力するとともにB側比較回路77からの信号を入力するシリアルインターフェース83とを備えている。

【0072】

d) 次に、本実施例における制御内容について説明する。

ここでは、脈波センサ1側にて行われる制御内容について、図8のフローチャートに基づいて説明する。

【0073】

まず、ステップ(S)100では、脈波センサ1とベース装置17とが接続されたか否かを判定する。つまり、S側接触検知端子19とB側接触検知端子39とが接触し、それによって、B側接触検知端子39からS側接触検知端子19に接触検知信号が入力されたか否かを判定する。ここで肯定判断されるとS110に進み、一方否定判断されるとその判定を繰り返す。

【0074】

S110では、脈波センサ1がベース装置17に接続されたので、CPU61の制御モードを、測定モードから送信モードに切り換える。

続くS120では、送信モードにて、メモリ63に記憶された脈波等のデータをベース装置17側に送信する。即ち、データのダウンロードを実行し、一旦本処理を終了する。

【0075】

つまり、本制御では、脈波センサ1がベース装置17に装着されると、脈波センサ1からベース装置17に自動的に脈波等の情報が送信される。

一方、脈波センサ1から送信された情報を受信したベース装置17では、その情報をパソコン59に送信する。

【0076】

e) この様に、本実施例では、脈波センサ1がベース装置17に装着されたことを、脈波センサ1がB側接触検知端子39とS側接触検知端子19との接触によって検知した場合には、メモリ63に記憶した脈波や体動等の生体の情報を、脈波センサ1のS側赤外LED23とベース装置17のB側PD45を用いて、ベース装置17に送信する。

【0077】

これにより、従来の特別な無線通信回路を用いたり通信用のケーブルで接続する必要が

無いので、故障が少なく、確実に且つ容易に生体の情報をベース装置 17 に送信することができる。よって、パソコン 59 では、ベース装置 17 を介して、生体の情報をダウンロードすることにより取得することができる。

【実施例 2】

【0078】

次に、実施例 2 について説明するが、前記実施例 1 と同様な内容の説明は省略する。

本実施例では、前記実施例 1 とは制御内容が異なるので、その制御内容について説明する。尚、同様なハード構成には同様な番号を付す。

【0079】

図 9 のフローチャートに示す様に、本実施例では、まず、S200 では、脈波センサ 1 とベース装置 17 とが接続されたか否かを判定する。ここで肯定判断されると S210 に進み、一方否定判断されるとその判定を繰り返す。

【0080】

S210 では、CPU61 の制御モードを、ダウンロード待機モードに切り換える。このダウンロード待機モードとは、ダウンロードを開始させるための信号（ダウンロード開始命令）が入力されるまでは、ダウンロードを待機させるためのモードである。

【0081】

続く S220 では、ベース装置 17 からダウンロード開始命令が来たか否かを判定する。ここで肯定判断されると S230 に進み、一方否定判断されるとその判定を繰り返す。

S230 では、ダウンロード開始命令が来たので、CPU61 の制御モードを、送信モードに切り換える。

【0082】

S240 では、データのダウンロードを実行し、一旦本処理を終了する。

つまり、本制御では、脈波センサ 1 がベース装置 17 に装着されると、ダウンロード待機モードに切り換え、ベース装置 17 からダウンロード開始命令が入力されると、脈波センサ 1 からベース装置 17 に脈波等の情報が送信される。

【0083】

本実施例によっても、前記実施例 1 と同様な効果を奏する。

【実施例 3】

【0084】

次に、実施例 3 について説明するが、前記実施例 1 と同様な内容の説明は省略する。

本実施例では、前記実施例 1 とは、脈波センサの構成と制御内容が異なるので、異なる構成や制御内容について説明する。

【0085】

図 10 の示す様に、本実施例の脈波センサ 91 は、電源の ON・OFF を行う電源スイッチ 93 と、制御モードを測定モードとダウンロード待機モードとに切り換えるモード切換スイッチ 95 とを備えている。

【0086】

図 11 のフローチャートに示す様に、まず、S300 では、モード切換スイッチ 95 が、ダウンロード待機モードか否かを判定する。ここで肯定判断されると S310 に進み、一方否定判断されると S320 に進む。

【0087】

S310 では、モード切換スイッチ 95 がダウンロード待機モードに設定されているので、CPU61 の制御モードを、ダウンロード待機モードに設定する。

一方、S320 では、制御モードを測定モードに設定する。

【0088】

そして、前記ダウンロード待機モードでは、図 12 のフローチャートに示す様に、S400 にて、脈波センサ 1 からベース装置 17 に対して、ダウンロード開始命令を要求するダウンロード開始要求信号を送信する。

【0089】

続く S 4 1 0 では、脈波センサ 1 がダウンロード開始命令を受信したか否かを判定する。ここで肯定判断されると S 4 2 0 に進み、一方否定判断されると前記 S 4 0 0 に戻る。

S 4 2 0 では、ダウンロード開始命令を受信したので、C P U 6 1 の制御モードを、送信モードに切り換える。

【 0 0 9 0 】

S 4 3 0 では、データのダウンロードを実行し、一旦本処理を終了する。

つまり、本制御では、脈波センサ 9 1 のモード切換スイッチ 9 5 が操作され、ダウンロード待機モードに切り換えられた場合には、ベース装置 1 7 に対してダウンロード開始命令の入力を要求し、ベース装置 1 7 からダウンロード開始命令が入力されると、脈波センサ 9 1 からベース装置 1 7 に脈波等の情報が送信される。

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【 0 0 9 1 】

本実施例によっても、前記実施例 1 と同様な効果を奏する。

【実施例 4】

【 0 0 9 2 】

次に、実施例 4 について説明するが、前記実施例 1 と同様な内容の説明は省略する。

本実施例では、前記実施例 3 とは制御内容が異なるので、その制御内容について説明する。

【 0 0 9 3 】

図 1 3 のフローチャートに示す様に、まず、S 5 0 0 では、モード切換スイッチ 9 5 が、ダウンロード待機モードか否かを判定する。ここで肯定判断されると S 5 1 0 に進み、一方否定判断されると S 5 2 0 に進む。

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【 0 0 9 4 】

S 5 1 0 では、モード切換スイッチ 9 5 がダウンロード待機モードに設定されているので、C P U 6 1 の制御モードを、ダウンロード待機モードに切り換える。

一方、S 5 2 0 では、制御モードを測定モードに切り換える。

【 0 0 9 5 】

そして、前記ダウンロード待機モードでは、図 1 4 のフローチャートに示す様に、S 6 0 0 にて、ベース装置 1 7 から、ダウンロード開始命令を受信したか否かを判定する。ここで肯定判断されると S 6 1 0 に進み、一方否定判断されると同じ判定を繰り返す。

【 0 0 9 6 】

S 6 1 0 では、ダウンロード開始命令を受信したので、C P U 6 1 の制御モードを、送信モードに切り換える。

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S 6 2 0 では、データのダウンロードを実行し、一旦本処理を終了する。

【 0 0 9 7 】

つまり、本制御では、脈波センサ 9 1 のモード切換スイッチ 9 5 が操作され、ダウンロード待機モードに切り換えられた場合に、ベース装置 1 7 からダウンロード開始命令が入力されると、脈波センサ 9 1 からベース装置 1 7 に脈波等の情報が送信される。

【 0 0 9 8 】

本実施例によっても、前記実施例 1 と同様な効果を奏する。

【実施例 5】

【 0 0 9 9 】

次に、実施例 5 について説明するが、前記実施例 1 と同様な内容の説明は省略する。

本実施例では、前記実施例 1 とは、S 側及び B 側の光学装置部が異なる。

図 1 5 に示す様に、本実施例では、ベース装置の B 側光学装置部のレンズ 1 0 1 は凹状であり、それに対向する脈波センサの S 側光学装置部のレンズ 1 0 3 は凸状である。

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【 0 1 0 0 】

つまり、B 側光学装置部のレンズ 1 0 1 と S 側光学装置部のレンズ 1 0 3 の凹凸形状は、ぴったりと嵌合する形状とされている。

従って、脈波センサをベース装置に装着した場合に、位置ずれなく装着できる。特に、B 側光学装置部のレンズ 1 0 1 と S 側光学装置部のレンズ 1 0 3 とを適切な位置に近接し

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て配置できるので、ノイズの影響を排除して、データの送受信を好適に行うことができる。

【実施例 6】

【0101】

次に、実施例 6 について説明するが、前記実施例 1 と同様な内容の説明は省略する。

本実施例では、前記実施例 1 とは、B 側光学装置部が異なる。

図 16 に示す様に、本実施例では、ベース装置の B 側光学装置部 111 には、レンズ 113 と B 側 PD 115 との間に、可視光線カットフィルム 115 が配置されている。

【0102】

従って、赤外光を用いてデータの送受信を行う際に、可視光線によるノイズを防ぐことができる。 10

【実施例 7】

【0103】

次に、実施例 7 について説明するが、前記実施例 1 と同様な内容の説明は省略する。

本実施例では、前記実施例 1 とは、S 側及び B 側光学装置部が異なる。

図 17 に示す様に、本実施例では、脈波センサの S 側光学装置部 121 の表面（同図右方）には、平板状の透明のカバー 123 が配置されており、カバー 123 と S 側赤外 LED 125 との間には、レンズ 127 が配置されている。

【0104】

また、ベース装置の B 側光学装置部 129 の表面（同図左方）には、平板状の透明のカバー 131 が配置されており、カバー 131 と B 側赤外 LED 133 との間には、レンズ 135 が配置されている。 20

【0105】

ここでは、カバー 131 と B 側 PD 137 との間に、可視光線カットフィルム 139 が配置されているが、カバー 123、131 に可視光線カットフィルムを配置したり、カバー 123、131 自身が可視光線をカットする性能を有するものを用いてもよい。

【0106】

従って、赤外光を用いてデータの送受信を行う際に、可視光線によるノイズを防ぐことができる。また、カバー 123、131 の表面がフラットであるので、レンズが露出する場合に比べて表面が傷つきにくいという利点がある。 30

【実施例 8】

【0107】

次に、実施例 8 について説明するが、前記実施例 1 と同様な内容の説明は省略する。

本実施例では、前記実施例 1 とは、S 側及び B 側の光学装置部が異なる。

図 18 に示す様に、本実施例では、ベース装置の B 側光学装置部のカバー 141 は凹状であり、それに対向する脈波センサの S 側光学装置部のカバー 143 は凸状である。

【0108】

つまり、B 側光学装置部のカバー 141 と S 側光学装置部のカバー 143 の凹凸形状は、ぴったりと嵌合する形状とされている。

従って、脈波センサをベース装置に装着した場合に、位置ずれなく装着できる。特に、B 側光学装置部のカバー 141 と S 側光学装置部のカバー 143 とを適切な位置に近接して配置できるので、ノイズの影響を排除して、データの送受信を好適に行うことができる。 40

【実施例 9】

【0109】

次に、実施例 9 について説明するが、前記実施例 1 と同様な内容の説明は省略する。

本実施例では、前記実施例 1 とは、S 側及び B 側の光学装置部が異なる。

図 19 に示す様に、本実施例では、ベース装置 151 の B 側光学装置部 153 には、一対の B 側 PD 155、157 が配置されている。

【0110】

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つまり、脈波センサ 159 の S 側光学装置部 161 の S 側赤外 LED 163 に対向して、一方の B 側 PD 155 が配置され、S 側緑 LED 165 に対向して、他方の B 側 PD 157 が配置されている。

【0111】

従って、本実施例では、2 組の発光及び受光の素子により、効率よく情報を送信することができる。

尚、例えば S 側緑 LED 165 と他方の B 側 PD 157 とを用いて、チェックサムの信号を送受信することにより、データの精度を高めることができる。

【実施例 10】

【0112】

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次に、実施例 10 について説明するが、前記実施例 1 と同様な内容の説明は省略する。

本実施例では、前記実施例 1 とは、脈波センサをベース装置に装着する構成が異なる。

図 20 に示す様に、本実施例では、平板状のベース装置 171 の上部に凹部 173 が設けられ、この凹部 173 に脈波センサ 175 が水平に搭載される構成である。

【0113】

そして、凹部 173 内に配置された B 側光学装置部 177 と、脈波センサ 175 の下面側の S 側光学装置部 179 とによって、情報の送受信を行う。

【実施例 11】

【0114】

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次に、実施例 11 について説明するが、前記実施例 1 と同様な内容の説明は省略する。

本実施例では、前記実施例 1 とは、脈波センサをベース装置に装着する構成が異なる。

図 21 に示す様に、本実施例では、ベース装置 181 は、上面が斜めになった円盤状の基台部 183 と、基台部 183 の上部に立設された円柱状の立設部 185 とから構成されている。

【0115】

基台部 183 の上面には、立設部 185 の根元に、脈波センサ本体 187 が嵌合する底部側嵌合凹部 189 が設けられている。

また、前記底部側嵌合凹部 189 は、立設部 185 側にわずかに傾斜しており、リストバンド 191 を立設部 185 に外嵌した際に、リストバンド 191 が上下方向にゆがまないよう程度に深さが設定されている。

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【0116】

従って、リストバンド 191 を立設部 185 に外嵌して、脈波センサ本体 187 を底部側嵌合凹部 189 に嵌めた場合は、S 側及び B 側の光学装置部（図示せず）は常に好ましい距離を保って配置されることになる。

【0117】

尚、本発明は前記実施例になんら限定されるものではなく、本発明を逸脱しない範囲において種々の態様で実施しうることはいうまでもない。

(1) 例えば、脈波センサは、測定によって得られた信号をそのまま記憶し、そのデータをベース装置側に送信するようにしてもよい。尚、ベース装置にパソコンを接続することなく、ベース装置にパソコンが行う機能を搭載するようにしてもよい。

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【0118】

(2) また、赤外 LED ではなく、その他の LED を使用してデータを送信するようにしてもよい。

【図面の簡単な説明】

【0119】

【図 1】 実施例 1 の脈波センサを示す斜視図である。

【図 2】 実施例 1 の脈波センサによって脈波を測定する状態を示す説明図である。

【図 3】 実施例 1 の生体情報収集システムの構成を示す説明図である。

【図 4】 実施例 1 の生体情報収集システムにおける端子の接触状態を示す説明図である。

【図 5】 実施例 1 の脈波センサがベース装置に装着される状態を示す説明図である。

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【図 6】 実施例 1 のバンド付きの脈波センサがベース装置に装着される状態を示す説明図である。

【図 7】 実施例 1 の生体情報収集システムの電氣的構成を示すブロック図である。

【図 8】 実施例 1 の脈波センサにおける処理を示すフローチャートである。

【図 9】 実施例 2 の脈波センサにおける処理を示すフローチャートである。

【図 10】 実施例 3 の脈波センサの構成を示す説明図である。

【図 11】 実施例 3 の脈波センサにおけるメインの処理を示すフローチャートである。

【図 12】 実施例 3 の脈波センサにおける待機モードの処理を示すフローチャートである。

。 【図 13】 実施例 4 の脈波センサにおけるメインの処理を示すフローチャートである。 10

【図 14】 実施例 4 の脈波センサにおける待機モードの処理を示すフローチャートである。

。 【図 15】 実施例 5 の脈波センサとベース装置の光学装置部を示す説明図である。

【図 16】 実施例 6 の脈波センサとベース装置の光学装置部を示す説明図である。

【図 17】 実施例 7 の脈波センサとベース装置の光学装置部を示す説明図である。

【図 18】 実施例 8 の脈波センサとベース装置の光学装置部を示す説明図である。

【図 19】 実施例 9 の生体情報収集システムの構成を示す説明図である。

【図 20】 実施例 10 の生体情報収集システムの構成を示す説明図である。

【図 21】 実施例 11 の生体情報収集システムの構成を示す説明図である。

【符号の説明】 20

【0120】

1、91、159、175…脈波センサ

17、151、171、181…ベース装置

21、165…S側緑LED

23、125、163…S側赤外LED

25…S側PD

43、133…B側赤外LED

45、115、137、155、157…B側PD

11、121、161、179…S側光学装置部

41、111、129、153、177…B側光学装置部 30

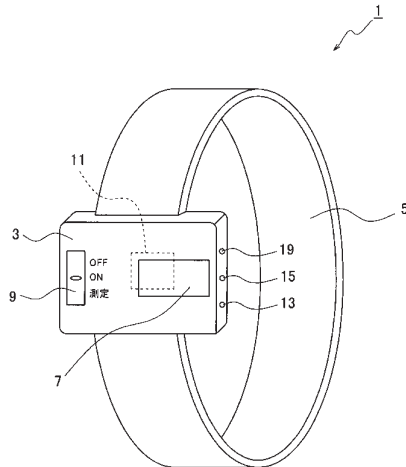
31、183…基台部

33、185…立設部

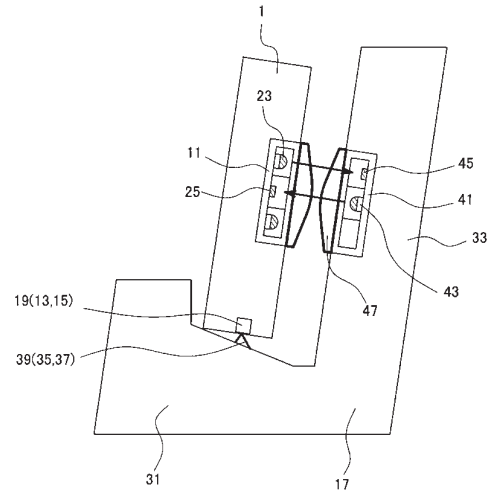
19…S側接触検知端子

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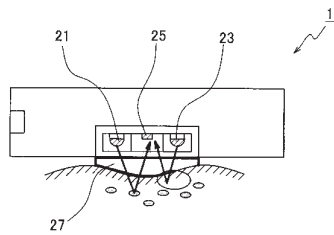
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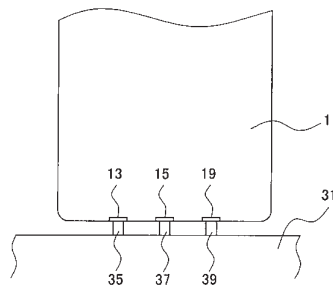
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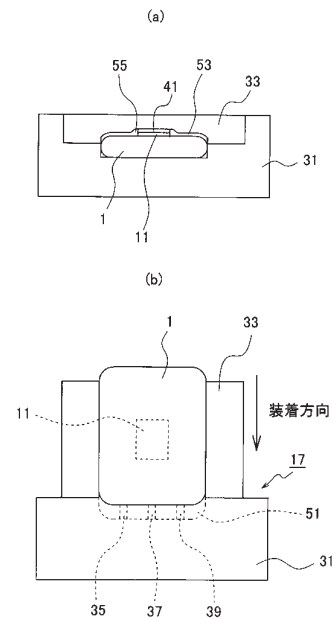
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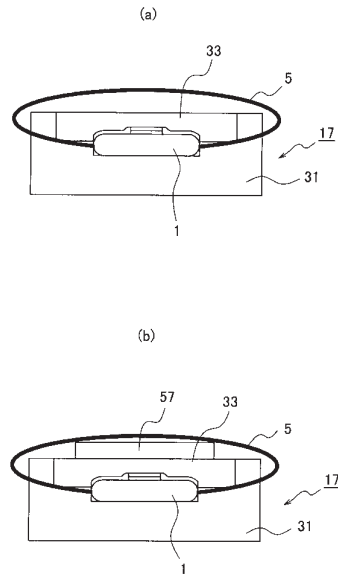
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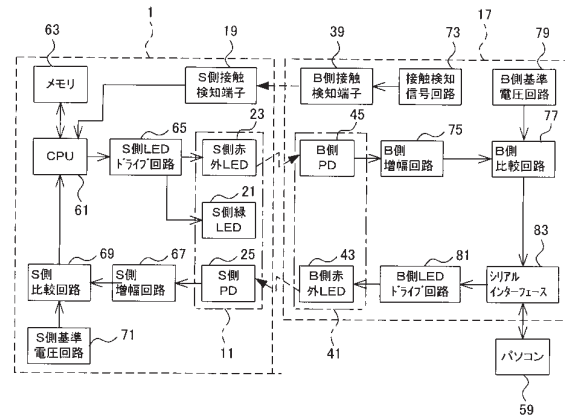
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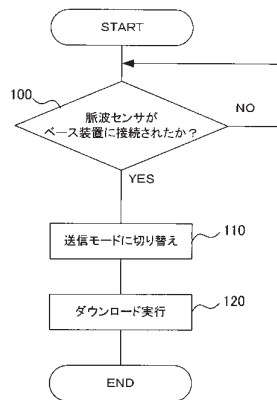
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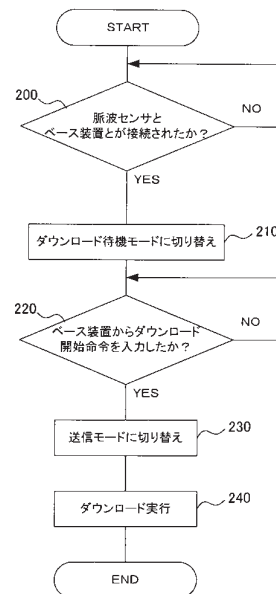
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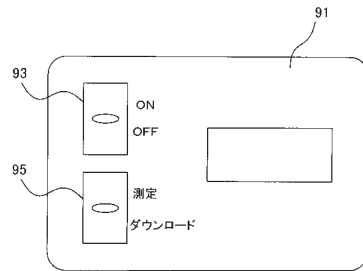
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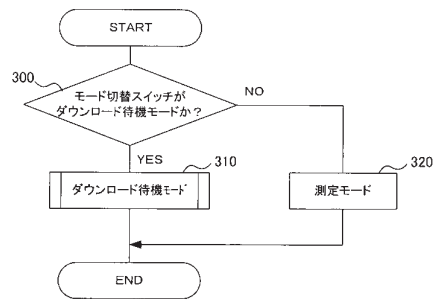
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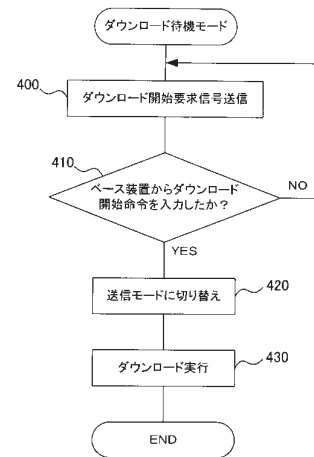
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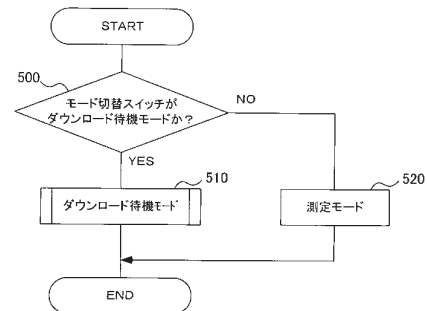
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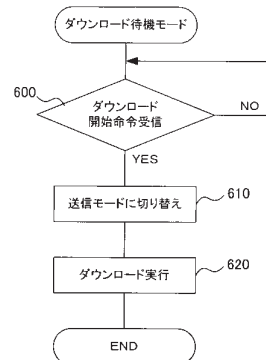
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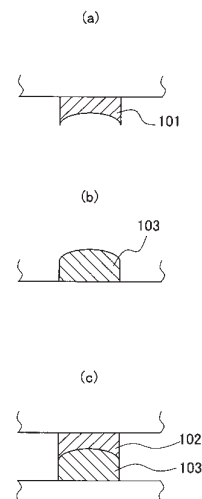
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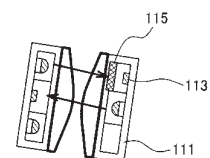
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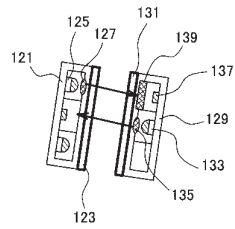
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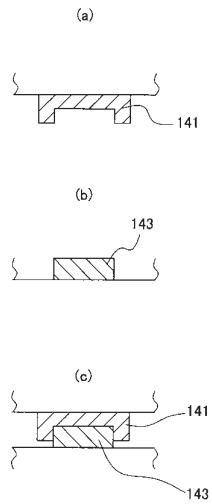
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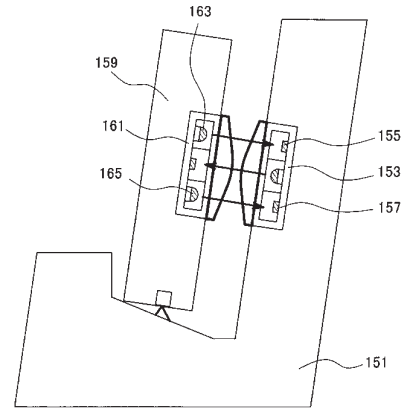
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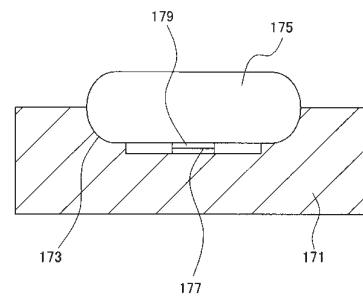
【図 18】



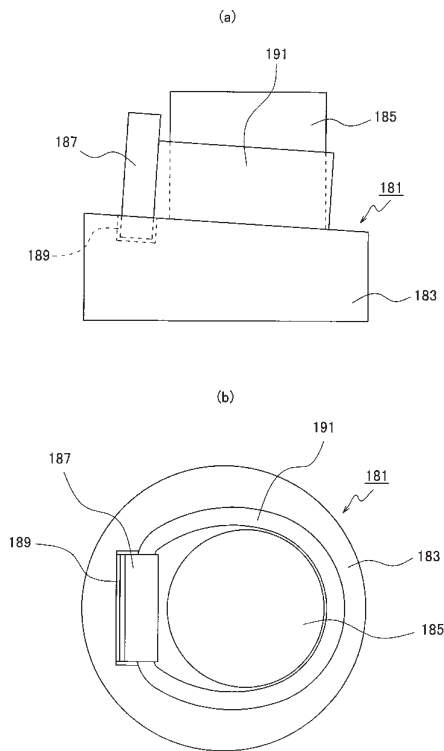
【図 19】



【図 20】



【図 21】



フロントページの続き

(72)発明者 森下 敏之

愛知県刈谷市昭和町1丁目1番地 株式会社デンソー内

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| (22) Date of application | April 18, 2005 (4.18.2005) | (74) Agent | 100082500 Patent attorney TSUTOMU ADACHI |
| | | (72) Inventor | KAZUYA INOKAWA % Denso Corporation 1 Showa-cho 1-chome, Kariya-shi, Aichi-ken |
| | | (72) Inventor | KYOJI INOBE % Denso Corporation 1 Showa-cho 1-chome, Kariya-shi, Aichi-ken |
| | | (72) Inventor | KATSUMASA NISHII % Denso Corporation 1 Showa-cho 1-chome, Kariya-shi, Aichi-ken |

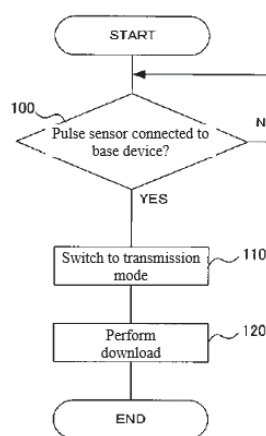
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**(54) (TITLE OF THE INVENTION) OPTICAL VITAL SENSOR, BASE DEVICE, VITAL SIGN INFORMATION
GATHERING SYSTEM, AND SENSOR COMMUNICATION METHOD****(57) (ABSTRACT)**

(PROBLEM) Provide an optical vital sensor, base device, vital sign information gathering system, and sensor communication method that are able to transmit and receive information with few malfunctions and with a simple structure.

(MEANS FOR SOLVING) In S100, determine whether or not a pulse sensor 1 and base device 17 are connected. In short, determine whether or not an S-side contact-detecting terminal 19 and a B-side contact-detecting terminal 39 are in contact, and consequently a "contact detected" signal has been input to the S-side contact-detecting terminal 19 from the B-side contact-detecting terminal 39. In S110, switch the control mode of the CPU 16 from measurement mode to transmission mode. In the ensuing S120, transmit data stored in memory, such as pulse, to a base device 17 in transmission mode. In short, download data. In other words, information, such as pulse, is automatically transmitted to the base device 17 from the pulse sensor 1 when the pulse sensor 1 is mounted onto the base device 17.

(SELECTED DRAWING) FIG. 8



(2)

(SCOPE OF PATENT CLAIMS)

(CLAIM 1)

Optical vital sensor furnished with a sensor-side optical device component having:

A sensor-side light-emitting means that emits light onto the body;

A sensor-side light-receiving means that receives reflected light, which consists of light that has been emitted by the aforesaid sensor-side light-emitting means and reflected by the aforesaid body; and

A vital sign sensing means that senses the vital signs of the aforesaid body based on the reflected light that was received by the aforesaid sensor-side light-receiving means;

characterized in that the information about the aforesaid vital signs sensed by the aforesaid vital sign sensing means is transmitted, using the aforesaid sensor-side light-emitting means, to a base device that is the recipient of transmissions from the aforesaid optical vital sensor.

(CLAIM 2)

Optical vital sensor set forth in Claim 1, characterized in that the aforesaid optical vital sensor has a measurement mode in which vital signs are sensed by the aforesaid vital sign sensing means, and a transmission mode in which the aforesaid vital sign information is transmitted to the aforesaid base device.

(CLAIM 3)

Optical vital sensor set forth in Claim 1 or 2, characterized in that it is furnished with a sensor-side contact-detecting component that detects when [the optical vital sensor] has been mounted onto the aforesaid base device.

(CLAIM 4)

Optical vital sensor set forth in Claim 3, characterized in that [the optical vital sensor] is set to the aforesaid transmission mode upon detecting that [the optical vital sensor] has been mounted onto the aforesaid base device.

(CLAIM 5)

Optical vital sensor set forth in any of Claims 2 through 4, characterized in that it is furnished with a mode-switching switch that switches between the aforesaid measurement mode and the aforesaid transmission mode.

(CLAIM 6)

Optical vital sensor set forth in any of Claims 1 through 5, characterized in that it is furnished with a charging component that is charged by means of a power supply structure on the aforesaid base device.

(CLAIM 7)

Optical vital sensor set forth in any of Claims 1 through 6, characterized in that it is furnished with two or more of the aforesaid sensor-side light-emitting means.

(CLAIM 8)

Light-emitting vital sensor set forth in any of Claims 1 through 7, characterized in that a lens is placed on the surface of the aforesaid sensor-side light-emitting means.

(CLAIM 9)

Light-emitting vital sensor set forth in any of Claims 1 through 7, characterized in that a translucent cover is placed on the surface of the aforesaid sensor-side light-emitting means.

(CLAIM 10)

Light-emitting vital sensor set forth in Claim 9, characterized in that the aforesaid cover serves the function of blocking visible light.

(CLAIM 11)

Base device to which the aforesaid vital sign information is transmitted from the optical vital sensor set forth in any of the aforesaid Claims 1 through 10,

Characterized in that it is furnished with a base-side optical device component that has a base-side light-receiving means for receiving the aforesaid vital sign information transmitted by the aforesaid sensor-side light-emitting means.

(CLAIM 12)

Base device set forth in Claim 11, characterized in that the aforesaid base-side optical device component is further furnished with a base-side light-emitting means that transmits a signal to the aforesaid sensor-side optical device component.

(CLAIM 13)

Base device set forth in Claim 12, characterized in that a command signal instructing the aforesaid vital sign information to be transmitted from the aforesaid sensor-side light-receiving means is transmitted to the aforesaid sensor-side light-receiving means

(3)

using the aforesaid base-side light-emitting means.

(CLAIM 14)

Base device set forth in any of Claims 11 through 13, characterized in that the aforesaid base device is furnished with a mounting structure onto which the aforesaid optical vital sensor is mounted in physical contact therewith.

(CLAIM 15)

Base device set forth in Claim 14, characterized in that the aforesaid optical vital sensor is disposed so as to be mounted at an angle when the aforesaid optical vital sensor is mounted onto the aforesaid base device.

(CLAIM 16)

Base device set forth in Claim 14, characterized in that the aforesaid optical vital sensor is disposed so as to be mounted level onto the aforesaid base device.

(CLAIM 17)

Base device set forth in any of Claims 11 through 16, characterized in that it is furnished with a base-side contact-detecting component that transmits a detection signal to the aforesaid optical vital sensor when the aforesaid optical vital sensor is mounted onto [the base device].

(CLAIM 18)

Base device set forth in any of Claims 11 through 17, characterized in that it has a power supply structure for charging the charging component of the aforesaid optical vital sensor.

(CLAIM 19)

Base device set forth in any of Claims 11 through 18, characterized in that it is furnished with two or more of the aforesaid base-side light-receiving elements.

(CLAIM 20)

Base device set forth in any of Claims 11 through 19, characterized in that the aforesaid base device is furnished with a recess into which the aforesaid optical vital sensor is fitted.

(CLAIM 21)

Base device set forth in Claim 20, characterized in that the aforesaid recess is a basal recess matching the base of the aforesaid optical vital sensor and/or a flank recess matching the sensor-side optical device component.

(CLAIM 22)

Base device set forth in Claim 20 or 21, characterized in that the aforesaid recess is a groove running the length of the direction in which the aforesaid optical vital sensor is mounted.

(CLAIM 23)

Vital sign information gathering system [*sic*: base device] set forth in Claim 21 or 22, characterized in that the central part of the groove in the aforesaid flank recess is itself further recessed.

(CLAIM 24)

Base device set forth in Claim 21 or 22, characterized in that the depth of the aforesaid basal recess is set such that, when the aforesaid optical vital sensor is fitted [into the recess] with a band attached thereto, the aforesaid band does not cause any impediment.

(CLAIM 25)

Base device set forth in any of Claims 11 through 24, characterized in that the aforesaid base device is furnished with a basal component onto which the aforesaid optical vital sensor is placed and an upright component extending upwards from said basal component.

(CLAIM 26)

Base device set forth in Claim 25, characterized in that there is a difference in level between the aforesaid basal component and the aforesaid upright component.

(CLAIM 27)

Base device set forth in Claim 25 or 26, characterized in that it is designed so that, when a band is attached to the aforesaid optical vital sensor, this band fits around the outside of the aforesaid upright component.

(CLAIM 28)

Base device set forth in any of Claims 25 through 27, characterized in that the flank of the aforesaid upright component is curved.

(CLAIM 29)

(4)

Base device set forth in any of Claims 11 through 28, characterized in that a lens is placed on the surface of the aforesaid base-side light-emitting means.

(CLAIM 30)

Base device set forth in any of Claims 11 through 28, characterized in that a translucent cover is placed on the surface of the aforesaid base-side light-emitting means.

(CLAIM 31)

Base device set forth in Claim 30, characterized in that the aforesaid cover serves the function of blocking visible light.

(CLAIM 32)

Vital sign information gathering system characterized in that it is furnished with the optical vital sensor set forth in any of the aforesaid Claims 1 through 10 and the base device set forth in any of the aforesaid Claims 11 through 31.

(CLAIM 33)

Vital sign information gathering system set forth in Claim 32, characterized in that the aforesaid vital sign information transmitted using the aforesaid sensor-side light-emitting means is received by the aforesaid base-side light-receiving means.

(CLAIM 34)

Vital sign information gathering system set forth in Claim 32 or 33, characterized in that a designated command signal transmitted using the aforesaid base-side light-emitting means is received by the aforesaid sensor-side light-receiving means.

(CLAIM 35)

Vital sign information gathering system set forth in Claim 34, characterized in that, when the aforesaid command signal is transmitted by the aforesaid base-side light-emitting means, the aforesaid optical vital sensor is set to the aforesaid transmission mode based on the aforesaid command signal.

(CLAIM 36)

Vital sign information gathering system set forth in any of Claims 32 through 35, characterized in that the aforesaid sensor-side optical device component and the aforesaid base-side optical device component are positioned in such a way as to be situated opposite one another when the aforesaid optical vital sensor is mounted onto the aforesaid base device.

(CLAIM 37)

Vital sign information gathering system set forth in any of Claims 32 through 36, characterized in that, when the aforesaid optical vital sensor is mounted onto the aforesaid base device, the aforesaid optical vital sensor fits into the aforesaid base device in such a way as to maintain a uniform distance and position between the light-emitting means and the light-receiving means.

(CLAIM 38)

Vital sign information gathering system set forth in any of Claims 32 through 37, characterized in that, when an infrared LED is used as the aforesaid sensor-side light-emitting means, a member to block visible light is placed on the surface of the aforesaid base-side light-receiving means.

(CLAIM 39)

Vital sign information gathering system set forth in any of Claims 32 through 38, characterized in that it has a configuration whereby, if a lens has been placed on the aforesaid base-side optical device component and on the aforesaid sensor-side optical device component, the convexity of one lens fits into the concavity of the other.

(CLAIM 40)

Vital sign information gathering system set forth in any of Claims 32 through 38, characterized in that, if a translucent cover has been placed on the aforesaid base-side optical device component and on the aforesaid sensor-side optical device component, the convexity of one cover fits into the concavity of the other.

(CLAIM 41)

Vital sign information gathering system set forth in any of Claims 32 through 40, characterized in that it has a configuration whereby the terminals of the aforesaid base device and the terminals of the aforesaid optical vital sensor mechanically contact one another.

(CLAIM 42)

Vital sign information gathering system set forth in Claim 41, characterized in that it has a configuration whereby the shape of the mutually contacting aforesaid terminals determines the direction in which the aforesaid optical vital sensor is mounted.

(CLAIM 43)

Vital sign information gathering system set forth in any of Claims 32 through 42, characterized in that it has a configuration

(5)

whereby the reception and transmission of signals between the aforesaid base device and the aforesaid optical vital sensor is performed using electromagnetism.

(CLAIM 44)

Vital sign information gathering system set forth in any of Claims 32 through 43, characterized in that it has a configuration whereby power is supplied from the aforesaid base device to the aforesaid optical vital sensor using electromagnetism.

(CLAIM 45)

Vital sign information gathering system set forth in any of Claims 32 through 44, characterized in that, if two or more sensor-side light-emitting means are provided on the aforesaid sensor-side optical device component, the aforesaid base-side optical device component is furnished with as many base-side light-receiving means as there are aforesaid sensor-side light-emitting means.

(CLAIM 46)

Vital sign information gathering system set forth in Claim 45, characterized in that a plurality of pairs of the aforesaid light-emitting means and light-receiving means are provided on the aforesaid sensor-side optical device component and the aforesaid base-side optical device component, and transmission of the aforesaid vital sign information is performed using the aforesaid plurality of pairs of light-emitting means and light-receiving means.

(CLAIM 47)

Vital sign information gathering system set forth in Claim 45, characterized in that a plurality of pairs of the aforesaid light-emitting means and light-receiving means are provided on the aforesaid sensor-side optical device component and the aforesaid base-side optical device component, and transmission of the aforesaid vital sign information is performed using one of the aforesaid pairs of light-emitting means and light-receiving means, whereas transmission of check information for checking the aforesaid transmitted vital sign information is performed using the other of the aforesaid pairs of light-emitting means and light-receiving means.

(CLAIM 48)

Sensor communication method for communication between the optical vital sensor set forth in any of the aforesaid Claims 1 through 10 and the base device set forth in any of the aforesaid Claims 11 through 31,

characterized in that the aforesaid vital sign information is transmitted to the aforesaid base-side light-receiving means using the aforesaid sensor-side light-emitting means.

(CLAIM 49)

Sensor communication method set forth in Claim 48, characterized in that the aforesaid vital sign information is transmitted from the aforesaid optical vital sensor to the aforesaid base device when the aforesaid optical vital sensor is mounted onto the aforesaid base device.

(CLAIM 50)

Sensor communication method set forth in Claim 48 or 49, characterized in that the aforesaid vital sign information is transmitted from the aforesaid optical vital sensor to the aforesaid base device when a designated command signal is transmitted from the aforesaid base device to the aforesaid optical vital sensor.

(CLAIM 51)

Sensor communication method set forth in Claim 50, characterized in that the aforesaid optical vital sensor is placed in standby mode when the aforesaid optical vital sensor is mounted onto the aforesaid base device, and the aforesaid vital sign information is transmitted from the aforesaid optical vital sensor to the aforesaid base device when a command signal is received from the aforesaid base device.

(CLAIM 52)

Sensor communication method set forth in Claim 51, characterized in that, in the event that the aforesaid optical vital sensor has been placed in standby mode by means of the mode-switching switch, the aforesaid vital sign information is transmitted from the aforesaid optical vital sensor to the aforesaid base device when a signal requesting the aforesaid command signal is transmitted from the aforesaid optical vital sensor to the aforesaid base device and a command signal is then received from the aforesaid base device.

(CLAIM 53)

Sensor communication method set forth in Claim 50, characterized in that, in the event that the aforesaid optical vital sensor has been placed in standby mode by means of the mode-switching switch, the aforesaid vital sign information is transmitted from the aforesaid optical vital sensor to the aforesaid base device when a command signal is received from the aforesaid base device.

(DETAILED DESCRIPTION OF THE INVENTION)

(6)

(TECHNICAL FIELD)

(0001)

The present invention relates to an optical vital sensor, base device, vital sign information gathering system, and sensor communication method that are able to obtain various kinds of vital sign information such as pulse.

(BACKGROUND ART)

(0002)

Prior to now, in clinical settings, instruments such as optical pulse sensors have been used to accurately gauge the condition of patients, etc.

When taking a measurement of pulse, pulse sensors of this kind store the measured data into memory. Technology exists that will download the data from the pulse sensor upon completion of measurement by connecting the pulse sensor via cable to a charger (base station) with communication functionality, and then connecting the base station to a PC via cable and transmitting an appropriate command from the PC.

(0003)

Separate from this, technology is also known that will transmit data wirelessly from a sensor that has obtained vital sign information to a base station that gathers this information (see Cited Literature 1 through 3).

(PATENT LITERATURE 1) Japanese Unexamined Patent Application Publication H2003-275183

(PATENT LITERATURE 2) Japanese Unexamined Patent Application Publication H2003-309485

(PATENT LITERATURE 3) Japanese Unexamined Patent Application Publication H2003-270486

(DISCLOSURE OF THE INVENTION)

(PROBLEM TO BE SOLVED BY THE INVENTION)

(0004)

However, in mechanically connected systems such as these in which the pulse sensor is connected to the base station via cable, there is the risk of contact failure due to damage or deterioration.

On the other hand, in the case of systems that transmit data wirelessly, the problem is that a dedicated wireless communication circuit is required in addition to the circuits for detecting vital sign information, etc.

(0005)

The present invention was devised to solve the aforesaid problems, having as its objective to provide an optical vital sensor, base device, vital sign information gathering system, and sensor communication method that are able to transmit and receive information with few malfunctions and with a simple structure.

(MEANS OF SOLVING THE PROBLEM)

(0006)

(1) In the invention in Claim 1, vital sign information sensed by a vital sign sensing means is transmitted, using a sensor-side light-emitting means, to a base device that is the recipient of transmissions from the optical vital sensor.

In short, an optical vital sensor (e.g. pulse sensor) is furnished with a sensor-side light-emitting means such as an LED in order to sense vital sign information (e.g. pulse, etc.), enabling this sensor light-emitting means to be used to transmit vital sign information to a base device.

(0007)

For this reason, it is not necessary to use a wireless communication circuit or to establish connections via communication cable, which makes it possible to easily transmit vital sign information with few malfunctions and with a simple structure.

Note that the type of vital sign information that can be transmitted includes any of the various kinds of information that can be measured and stored in memory by an optical vital sensor, including the various kinds of signals obtained by reflected light such as pulse (pulse rate, pulse interval) and signals indicating body motion or the like, as well as information obtained by analysis of these signals. Furthermore, it is also possible to transmit raw measurement data (data stored in memory).

(0008)

(2) In the invention in Claim 2, an optical vital sensor as a measurement mode in which vital signs are sensed by a vital sign sensing means, and a transmission mode in which vital sign information is transmitted to a base device, enabling operation to be performed in accordance with the respective mode by switching between modes.

(0009)

Note that a standby mode may also be furnished, whereby [the optical vital sensor] waits to transmit vital sign information to

(7)

the base device until receipt of a command signal (a signal instructing to transmit) from the base device.

(3) In the invention in Claim 3, it is possible to detect when the optical vital sensor has been mounted onto the base device.
(0010)

Note that the sensor-side contact-detecting component can consist, for example, of terminals that come into contact with the terminals on the base side (base-side contact-detecting component). Alternately, detection may be performed by means of electromagnetism rather than by means of contact with the terminals on the base side.

(0011)

(4) In the invention in Claim 4, transmission mode is enabled when it is detected that [the optical vital sensor] has been mounted onto the base device. This makes it possible to automatically transmit vital sign information when the optical vital sensor is mounted onto the base device.

(0012)

(5) In the invention in Claim 5, a mode-switching switch is provided for the purpose of switching between measurement mode and transmission mode. Accordingly, because the modes can be switched by means of this mode-switching switch, it is possible to cause the optical vital sensor to perform the desired processing at the desired timing.

(0013)

(6) In the invention in Claim 6, a charging component is provided, making it possible to charge [the optical vital sensor] by means of the power supply structure of the base device.

Note that, to perform charging, terminals that come into contact with one another may be provided on the optical vital sensor and the base device, but it is also acceptable to adopt a configuration whereby power is supplied by electromagnetism.

(0014)

(7) In the invention in Claim 7, two or more light-emitting means such as LEDs are provided as the sensor-side light-emitting means.

Accordingly, by transmitting the vital sign information using a plurality of sensor-side light-emitting means, it is possible to transmit efficiently. It is also possible to distinguish between the roles performed by the light-emitting means, e.g. with one means used to transmit vital sign information and another means used to transmit information used to check a checksum or the like. Furthermore, when using sensor-side light-emitting means of various kinds, such as an infrared LED or a green LED, the manner of use can be adjusted according to the properties of each respective means. For example, work can be divided between the various means, with an infrared LED used to detect vital signs and transmit vital sign information, and a green LED used to detect pulse.

(0015)

(8) In the invention in Claim 8, a lens is placed on the surface of the sensor-side light-emitting means.

This lens makes it possible to increase the light-gathering ability of the LED as well as to protect the LED or PD.

(0016)

(9) In the invention in Claim 9, a translucent cover is placed on the surface of the sensor-side light-emitting means.

This cover makes it possible to protect the LED or PD. Note that a lens may be placed on the inside of the cover.

(0017)

(10) In the invention in Claim 10, the cover serves the function of blocking visible light, making it possible to block noise caused by visible light.

(11) The invention in Claim 11 is a base device to which vital sign information is transmitted from the optical vital sensor. This base device receives vital sign information by means of a base-side light-receiving means in a base-side optical device component.

(0018)

(12) In the invention in Claim 12, a base-side light-emitting means is able to transmit a variety of signals (e.g. a command signal requesting the transmission of vital sign information, etc.) to (the sensor-side light-receiving means of) the sensor-side optical device component.

(0019)

(8)

(13) In the invention in Claim 13, the base-side light-emitting means can be used to transmit a command signal to the sensor-side light-receiving means instructing the sensor-side light-receiving means to transmit vital sign information.

(14) In the invention in Claim 14, the base device is furnished with a mounting structure enabling the optical vital sensor to be mounted in physical contact therewith. Consequently, this enables the optical vital sensor to be mounted onto the base device.

(0020)

(15) In the invention in Claim 15, the optical vital sensor is mounted onto the base device at an angle (tilted slightly off vertical). Consequently, this makes it possible to use gravity to place the sensor-side optical device component and the base-side optical device component in close proximity (or touching).

(0021)

(16) In the invention in Claim 16, the optical vital sensor is mounted onto the base device level to the ground.

(17) In the invention in Claim 17, the base device is furnished with a base-side contact-detecting component, by which means it is possible to transmit a detection signal (e.g. "contact detected" signal) indicating that the optical vital sensor has been mounted onto the base-side contact-detecting component of the optical vital sensor.

(0022)

Note that, for the base-side contact-detecting component, it is possible to use terminals that come into direct contact, or to use a detecting component that transmits a detection signal by means of electromagnetism.

(18) In the invention in Claim 18, a power supply structure is provided, making it possible to charge the charging component of the optical vital sensor by means of this power supply structure.

(0023)

Note that, for the power supply structure, it is possible to use terminals that come into direct contact, or to use a structure that performs charging by means of electromagnetism

(19) In the invention in Claim 19, two or more base-side light-receiving means are provided (according to the number of sensor-side light-emitting means).

(0024)

Consequently, this makes it possible to efficiently receive vital sign information using a plurality of base-side light-receiving means. Functions can be divided between means, e.g. with one means receiving vital sign information and another means receiving information used to check a checksum or the like.

(0025)

(20) In the invention in Claim 20, the base device is furnished with a recess into which the optical vital sensor is fitted, thereby making it possible to easily mount the optical vital sensor.

(21) The invention in Claim 21 cites examples of recesses. The basal recess fits the base of the aforesaid optical vital sensor (the tip side of the mounting direction), and the flank recess fits the sensor-side optical device component of the optical vital sensor.

(0026)

(22) The invention in Claim 22 cites a groove-shaped recess.

(23) In the invention in Claim 23, the groove in the flank recess is further recessed in the center so that the sensor-side optical device component can be placed into this recessed portion.

(0027)

(24) In the invention Claim 24, the depth of the basal recess is set such that, when the optical vital sensor is fitted therein, the band does not cause any impediment. This makes it easy to securely mount the optical vital sensor, as well as making it possible to securely perform transmission.

(0028)

(25) The invention in Claim 25 cites an example of a base device furnished with a basal component and an upright component.

(26) The invention in Claim 26 has a difference in level between the basal component and the upright component so as to facilitate the mounting of an optical vital sensor with a band attached thereto.

(0029)

(27) In the invention in Claim 27, the band of the optical vital sensor can be fitted around the upright component.

(9)

(28) In the invention in Claim 28, the side surface of the upright component is curved so as to facilitate sliding the rounded band.

(0030)

(29) In the invention in Claim 29, a lens is provided on the surface of the base-side light-emitting means.

This lens makes it possible to increase the light-gathering ability of the LED, as well as to protect the LED or PD.

(0031)

(30) In the invention in Claim 30, a translucent cover is provided on the surface of the base-side light-emitting means.

This cover makes it possible to protect the LED or PD. Note that a lens may be provided on the inside of the cover.

(0032)

(31) In the invention in Claim 31, the cover serves the function of blocking visible light.

(32) In the invention in Claim 32, a vital sign information gathering system is furnished with an optical vital sensor and a base device.

(0033)

(33) In the invention in Claim 33, vital sign information transmitted using a sensor-side light-emitting means is able to be received by means of a base-side light-receiving means.

(34) In the invention in Claim 34, a designated command signal (e.g. a signal that causes vital sign information to be transmitted from the optical vital sensor) transmitted using a base-side light-emitting means is able to be received by means of a sensor-side light-receiving means.

(0034)

(35) In the invention in Claim 35, when a command signal is transmitted by the base-side light-emitting means, the optical vital sensor is set to transmission mode based on the command signal. This makes it possible to transmit vital sign information from the optical vital sensor to the base device.

(0035)

(36) In the invention in Claim 36, the sensor-side optical device component and the base-side optical device component are positioned in such a way as to be situated opposite one another when the optical vital sensor is mounted onto the base device, thereby making it possible to perform transmission and reception of information in an optimal manner by optical means.

(0036)

(37) In the invention in Claim 37, a structure is adopted whereby, when the optical vital sensor is mounted onto the base device, the optical vital sensor fits into the base device in such a way as to maintain a uniform distance and position between the light-emitting means and the light-receiving means.

(0037)

By this means, when the optical vital sensor is fitted into the base device, the distance and position remain uniform between the light-emitting means and the light-receiving means, thereby making it possible to accurately perform transmission and reception of information.

(0038)

Note that light-emitting means and light-receiving means refer either to sensor-side light-emitting means and base-side light-receiving means, or to base-side light-emitting means and sensor-side light-receiving means.

(38) In the invention in Claim 38, when an infrared LED is used as the sensor-side light-emitting means, a member to block visible light is placed on the surface of the base-side light-receiving means, thereby making it possible to block noise caused by visible light.

(0039)

(39) In the invention in Claim 39, the configuration is such that, if a lens has been placed on the base-side optical device component and on the sensor-side optical device component, the convexity of one lens fits into the concavity of the other, eliminating the chance of misalignment, thereby making it possible to perform transmission and reception of information in an optimal manner by optical means.

(0040)

(40) In the invention in Claim 40, the configuration is such that, if a translucent cover has been placed on the base-side optical device component and on the sensor-side optical device component, the convexity of one cover fits into the concavity of the

(10)

other, eliminating the chance of misalignment, thereby making it possible to perform transmission and reception of information in an optimal manner by optical means.

(0041)

(41) In the invention in Claim 41, the configuration is such that the terminals of the base device and the terminals of the optical vital sensor are in mechanical contact.

(42) In the invention in Claim 42, the configuration is such that the shape of the mutually touching terminals determines the direction in which the optical vital sensor is mounted, ensuring that it is not mounted the wrong way.

(0042)

(43) In the invention in Claim 43, the configuration is such that transmission and reception of signals between the base device and the optical vital sensor is performed using electromagnetism.

(44) In the invention in Claim 44, the configuration is such that power is supplied from the base device to the optical vital sensor using electromagnetism.

(0043)

(45) In the invention in Claim 45, if two or more sensor-side light-emitting means are provided on the sensor-side optical device component, the base-side optical device component is furnished with as many base-side light-receiving means as there are sensor-side light-emitting means.

(0044)

Consequently, by transmitting vital sign information using a plurality of sensor-side light-emitting means, it is possible to transmit efficiently. It is also possible to distinguish between the roles performed by the light-emitting means, e.g. with one means used to transmit vital sign information and another means used to transmit information used to check a checksum or the like. Furthermore, when using sensor-side light-emitting means of various kinds, such as an infrared LED and a green LED, the manner of use can be adjusted according to the properties of each respective means.

(0045)

(46) In the invention in Claim 46, a plurality of pairs of light-emitting means and light-receiving means are provided on the sensor-side optical device component and the base-side optical device component, and transmission of vital sign information is performed using the plurality of pairs of light-emitting means and light-receiving means.

(0046)

An example of how to provide a plurality of light-emitting means and light-receiving means is to provide a first light-emitting means on the optical vital sensor and a corresponding first light-receiving means on the base device, and to provide a second light-emitting means on the optical vital sensor and a corresponding second light-receiving means on the base device.

(0047)

(47) In the invention in Claim 47, a plurality of pairs of light-emitting means and light-receiving means are provided on the sensor-side optical device component and the base-side optical device component, and each of the plurality of pairs of light-emitting means and light-receiving means are used separately to perform transmission of vital sign information and transmission of check information for checking the transmitted vital sign information.

(0048)

An example of providing a plurality of light-emitting means and light-receiving means is a case in which a first light-emitting means is provided on the optical vital sensor (to transmit vital sign information) and a corresponding first light-receiving means is provided on the base device, while a second light-emitting means (to transmit checksum information or the like) is provided on the optical vital sensor and a corresponding second light-receiving means is provided on the base device.

(0049)

(48) The invention in Claim 48 is a sensor communication method for communication between the optical vital sensor and base device, wherein vital sign information is transmitted to the base-side light-receiving means using the sensor-side light-emitting means.

(0050)

(49) In the invention in Claim 49, vital sign information is transmitted from the optical vital sensor to the base device when the optical vital sensor is mounted onto the base device.

(50) In the invention in Claim 50, vital sign information is transmitted from the optical vital sensor to the base device when a

(11)

designated command signal (a signal requesting the transmission of vital sign information) is transmitted from the base device to the optical vital sensor.

(0051)

(51) In the invention in Claim 51, the optical vital sensor is placed in standby mode when the optical vital sensor is mounted onto the base device, and vital sign information is transmitted from the optical vital sensor to the base device when a command signal is received from the base device.

(0052)

(52) In the invention in Claim 52, in the event that the optical vital sensor has been placed in standby mode by means of the mode-switching switch, vital sign information is transmitted from the optical vital sensor to the base device when a signal requesting a command signal is transmitted from the optical vital sensor to the base device and a command signal is then received from the base device.

(0053)

(53) In the invention in Claim 53, in the event that the optical vital sensor has been placed in standby mode by means of the mode-switching switch, vital sign information is transmitted from the optical vital sensor to the base device when a command signal is received from the aforesaid base device.

(PREFERRED EMBODIMENTS OF THE INVENTION)

(0054)

Preferred embodiments of the invention (embodiment examples) will be described below together with drawings.

(EMBODIMENT EXAMPLE 1)

(0055)

Below is a description of an optical vital sensor, base device, vital sign information gather system, and sensor communication method that are capable of sensing a subject's vital sign information such as pulse, and transmitting this information to a base device.

(0056)

a) First, the optical vital sensor of this embodiment example will be described.

As shown in FIG. 1, the optical vital sensor is a pulse sensor 1 that is able to sense the pulse, etc. by being attached, for example, to a person's finger or wrist.

(0057)

This pulse sensor 1 is a known optical reflective sensor consisting of a box-shaped sensor unit 3 and a flexible annular wristband 5 (connected to the sensor unit 3).

On the top surface of the sensor unit 3 is a display 7 and a control switch 9, while on the rear surface is a sensor-side (S-side) optical device component 11 for optically sensing the pulse, etc.

On either the left or right side of the sensor unit 3 (the direction perpendicular to the wristband 5) are provided a pair of S-side charging terminals 13, 15 for charging the sensor unit 3 and an S-side contact-detecting terminal 19 for sensing when the sensor unit 3 has been mounted onto the base device 17 (see FIG. 3). Note that the aforesaid control switch 9 is a switch that can be switched between three positions: power on, power off, and start pulse measurement.

(0058)

As shown in FIG. 2, the pulse sensor 1 is comprised of a pair of light-emitting elements, i.e. a green light-emitting diode (S-side green LED) 21 and an infrared light-emitting diode (S-side infrared LED) 23, a single photodiode (S-side PD) 25 that receives the reflected light from these, and an S-side lens 27.

(0059)

Among these, the basic function of the S-side green LED 21 is to sense the pulse from the light reflected off of the body (i.e. change in the amount of hemoglobin in the capillary artery), while the S-side infrared LED 23 serves to sense body motion from the change in this reflected light.

(0060)

b) Next, the base device 17 of this embodiment example will be described.

As schematically shown in FIG. 3, the base device 17 is a charger with communication functionality that is used when the pulse sensor 1 is mounted, and is comprised of a basal component 31 onto which the pulse sensor 1 is placed and a flat upright component 33 mounted vertically at an angle from the basal component 31.

(12)

(0061)

On the top surface of the basal component 31 of the base device 17, as shown in FIG. 4, are the counterparts to the charging terminals 13, 15 and S-side contact-sensing terminal 19 on the pulse sensor 1, namely base-side (B-side) charging terminals 35, 37 that serve to charge the pulse sensor 1, and a B-side contact-sensing terminal 39 that contacts the S-side contact-sensing terminal 19. Note that the B-side charging terminals 35, 37 and the B-side contact-sensing terminal 39 are impelled upwards by a spring (not shown in the drawing) enabling upward and downward movement thereof.

(0062)

To return to the aforesaid FIG. 3, a similar B-side optical device component 41 is provided corresponding to the S-side optical device component 11 of the pulse sensor 1. In short, the B-side optical device component 41 is comprised of a B-side infrared LED 43, B-side PD 45, and B-side lens 47, with the B-side PD 45 being positioned opposite the S-side infrared LED 23, and the B-side infrared LED 43 being positioned opposite the S-side PD 25.

(0063)

Furthermore, as shown in FIG. 5 (b), a groove-shaped basal fitting recess 51 is provided on the basal portion 31 of the base device 17, its shape corresponding to the base of the pulse sensor 1 so as to fit the pulse sensor 1, thereby enabling the pulse sensor 1 to be moved in the fitting direction into the basal fitting recess 51 without misalignment.

(0064)

Furthermore, as shown in FIG. 5 (a), a lateral fitting recess 53 is provided on the mounting side of the pulse sensor 1 of the upright component 33 (downward in the drawing), its shape corresponding to the external shape of the pulse sensor 1, and a central recess 55 is provided in the center of this lateral fitting recess 53, i.e. in a location corresponding to the S-side optical device component 11 and the B-side optical device component 41.

(0065)

Furthermore, as shown in FIG. 6, the wristband 5 of the pulse sensor 1 is positioned in such a way as to fit around the outside of the upright component 33 of the base device 17. If a post 57 is provided on the rear side of the upright component 33 (top of FIG. 6 (b)), the wristband 5 is positioned in such a way as to fit around the outside of the upright component 33 and the post 57. Note that the depth of the aforesaid basal fitting recess 51 should be set in such a way as to ensure that the wristband 5 does not touch the surface of the basal component 31 when the pulse sensor 1 is fitted around the outside of the upright component 33, etc.

(0066)

c) Next, the electrical structure of the vital sign information gathering system comprised of the aforesaid pulse sensor 1 and base device 17 will be described.

The vital sign information gathering system of this embodiment example is comprised of a base device 17 and a pulse sensor 1 mounted onto (placed on) the base device 17.

When the pulse sensor 1 is mounted, the S-side optical device component 11 and the B-side optical device component 41 are brought into close proximity opposite one another, by which means the S-side infrared LED 23 and the B-side PD 45 are made to face one another, and the S-side PS 25 and B-side infrared LED 43 are made to face one another. Simultaneously, the S-side contact-sensing terminal 19 and the B-side contact-sensing terminal 39 come into contact with one another. Note that the S-side charging terminals 13, 15 and B-side charging terminals 35, 37 are also brought into contact with one another.

(0067)

In this vital sign information gathering system, the pulse sensor 1 senses the pulse, etc., and outputs information about the pulse, etc. to the base device 17 by means of the S-side optical device component 11, while the base device 17 receives the information transmitted from the pulse sensor 1 by means of the B-side optical device component 41. Note that the base device 17 is connected to a PC 59, and information transmitted from the pulse sensor 1 is downloaded to the PC 59 via the base device 17. This will be explained in detail below.

(0068)

- The aforesaid pulse sensor 1 is comprised of a CPU 61 that controls the pulse sensor 1; a memory 63 that stores information on sensed pulse, etc.; the aforesaid S-side contact-sensing terminal 19; the aforesaid S-side infrared LED 23; the aforesaid S-side green LED 21; an S-side LED drive circuit 65 that drives the S-side infrared LED 23 and the S-side green LED 21; the aforesaid S-side PD 25; an S-side amplification circuit 67 that amplifies the signal input from the S-side PD 25;

(13)

an S-side comparison circuit 69 that generates a digital signal by comparing the analog signal input from the S-side amplification signal 67 with a reference voltage; and an S-side reference voltage circuit 71 that generates a reference voltage.

(0069)

The aforesaid CPU 61 performs the controls necessary to sense pulse, body motion, etc. while in measurement mode. In short, [the CPU 61] drives the S-side drive circuit 65, controls the S-side infrared LED 23 and the S-side green LED 21, performs the processing to sense pulse, body motion, etc. from the signal received by the S-side PD 25, and temporarily stores the analysis data in the memory 63. Note that the digital signal converted by the S-side comparison circuit 69 is input to the CPU 61.

(0070)

The CPU 61 also performs the controls necessary to transmit information about pulse, etc. to the base device 17 while in transmission mode. In short, [the CPU 61] drives the S-side drive circuit 65, controls the S-side infrared LED 23, and transmits an optical signal containing the information stored in the memory 63 to the base device 17.

(0071)

- The aforesaid base device 17 is comprised of a B-side contact-sensing terminal 39 that transmits a signal (contact sensed signal indicating that contact has been made) upon contacting the S-side contact-sensing terminal 19; contact sensed signal circuit 73 that generates the contact sensed signal transmitted to the B-side contact-sensing terminal 39; the aforesaid B-side PD 45; B-side amplification circuit 75 that amplifies the signal input from the B-side PD 45; B-side comparison circuit 77 that generates a digital signal by comparing the analog signal input from the B-side amplification signal 75 with a reference voltage; B-side reference voltage circuit 79 that generates a reference voltage; the aforesaid B-side infrared LED 43; B-side LED drive circuit 81 that drives the B-side infrared LED 43; and serial interface 83 that outputs the control signal of the B-side LED drive circuit 81 and inputs the signal from the B-side comparison circuit 77.

(0072)

d) Next, the controls of this embodiment example will be described.

Here, the controls performed by the pulse sensor 1 will be described based on the flowchart in FIG. 8.

(0073)

First, in step (S) 100, a determination is made as to whether or not the pulse sensor 1 and the base device 17 have been connected. In short, a determination is made as to whether or not the S-side contact-sensing terminal 19 and the B-side contact-sensing terminal 39 are in contact, and consequently a contact sensed signal has been input from the B-side contact sensing terminal 39 to the S-side contact-sensing terminal 19. In the event of a positive judgment at this point, processing proceeds to S110, whereas in the event of a negative judgment, this determination is performed again.

(0074)

In S110, because the pulse sensor 1 has been connected to the base device 17, the control mode of the CPU 61 is switched from measurement mode to transmission mode.

In the ensuing S120, in transmission mode, data stored in the memory 63, such as pulse, is transmitted to the base device 17. In short, data is downloaded, thereby concluding this process.

(0075)

In short, by means of these controls, when the pulse sensor 1 is mounted onto the base device 17, information about pulse, etc. is automatically transmitted from the pulse sensor 1 to the base device 17.

The base device 17, meanwhile, upon receiving the information transmitted from the pulse sensor 1, transmits this information to the PC 59.

(0076)

e) Thus, in this embodiment example, in the event that the pulse sensor 1 senses that the pulse sensor 1 has been mounted onto the base device 17 by reason of the fact that the B-side contact-sensing terminal 39 and the S-side contact-sensing terminal 19 are in contact, vital sign information stored in the memory 63, such as pulse and body motion, is transmitted to the base device 17 using the S-side infrared LED 23 of the pulse sensor 1 and the B-side PD 45 of the base device 17.

(0077)

As a result, there is no need to use a special wireless communication circuit or a communication cable as previously, which

(14)

makes it possible to transmit vital sign information to the base device 17 accurately, easily, and without malfunction. Hence, the PC 59 is able to obtain vital sign information by downloading it from the base device 17.

(EMBODIMENT EXAMPLE 2)

(0078)

Next, Embodiment Example 2 will be described, omitting aspects identical to the above-described Embodiment Example 1.

For this embodiment example, the controls differ from those of the above-described Embodiment Example 1, so the controls will be described. Note that identical hardware components are referenced using the same numbers.

(0079)

As shown in the flowchart in FIG. 9, in this embodiment example, first, in step S200, a determination is made as to whether or not the pulse sensor 1 and the base device 17 are connected. In the event of a positive result, processing proceeds to S210, whereas in the event of a negative result, this determination is repeated.

(0080)

In S210, the control mode of the CPU 61 is switched to download standby mode. This download standby mode is a mode in which [the CPU 61] waits to perform downloading until the signal to start downloading (download start command) is input.

(0081)

In the ensuing S220, a determination is made as to whether or not the download start command has been received from the base device 17. In the event of a positive result, processing proceeds to S230, whereas in the event of a negative result, this determination is repeated.

In S230, the control mode of the CPU 61 is switched to transmission mode because the download start command was received.

(0082)

In S240, data is downloaded, thereby concluding this process.

In short, by means of these controls, the mode is switched to download standby mode when the pulse sensor 1 is mounted onto the base device 17, and information, such as pulse, is transmitted from the pulse sensor 1 to the base device 17 when a download start command is input from the base device 17.

(0083)

This embodiment example provides the same effect as the above-described Embodiment Example 1.

(EMBODIMENT EXAMPLE 3)

(0084)

Next, Embodiment Example 3 will be described, omitting aspects identical to the above-described Embodiment Example 1.

For this embodiment example, the structure and controls of the pulse sensor differ from those of the above-described Embodiment Example 1, so differences in the structure and controls will be described.

(0085)

As shown in FIG. 10, the pulse sensor 91 in this embodiment example is comprised of a power switch 93 that turns power on/off, and a mode-switching switch 95 that switches the control mode between measurement mode and download standby mode.

(0086)

As shown in the flowchart in FIG. 11, first, in S300, a determination is made as to whether or not the mode-switching switch 95 is set to download standby mode. In the event of a positive result, processing proceeds to S310, whereas in the event of a negative result, processing proceeds to S320.

(0087)

In S310, because the mode-switching switch 95 is set to download standby mode, the control mode of the CPU 61 is set to download standby mode.

In contrast, in S320, the control mode is set to measurement mode.

(0088)

During the aforesaid download standby mode, as shown in the flowchart in FIG. 12, in S400, a download start request signal is transmitted from the pulse sensor 1 to the base device 17 to request a download start command.

(0089)

(15)

In the ensuing S410, a determination is made as to whether or not the pulse sensor 1 has received a download start command. In the event of a positive result, processing proceeds to S420, whereas in the event of a negative result, processing returns to the aforesaid S400.

In S420, since a download start command has been received, the control mode of the CPU 61 is switched to transmission mode. (0090)

In S430, data is downloaded, thereby concluding this process.

In short, by means of these controls, if the mode-switching switch 95 of the pulse sensor 91 is operated and the mode is switched to download standby mode, a request to send a download start command is sent to the base device 17. Upon input of a download start command from the base device 17, information, such as pulse, is transmitted from the pulse sensor 91 to the base device 17.

(0091)

This embodiment example provides the same effect as the above-described Embodiment Example 1.

(EMBODIMENT EXAMPLE 4)

(0092)

Next, Embodiment Example 4 will be described, omitting aspects identical to the above-described Embodiment Example 1.

For this embodiment example, the controls differ from those of the above-described Embodiment Example 3, so the controls will be described.

(0093)

As shown in the flowchart in FIG. 13, first, in S500, a determination is made as to whether or not the mode-switching switch 95 is set to download standby mode. In the event of a positive result, processing proceeds to S510, whereas in the event of a negative result, processing proceeds to S520.

(0094)

In S510, because the mode-switching switch 95 is set to download standby mode, the control mode of the CPU 61 is switched to download standby mode.

In contrast, in S520, the control mode is switched to measurement mode.

(0095)

During the aforesaid download standby mode, as shown in the flowchart in FIG. 14, in S600, a determination is made as to whether or not a download start signal has been received from the base device 17. In the event of a positive result, processing proceeds to S610, whereas in the event of a negative result, the same determination is repeated.

(0096)

In S610, because a download start command was received, the control mode of the CPU 61 is switched to transmission mode.

In S620, data is downloaded, thereby concluding this process.

(0097)

In short, by means of these controls, if the mode-switching switch 95 of the pulse sensor 91 is operated and the mode is switched to download standby mode, upon input of a download start command from the base device 17, information, such as pulse, is transmitted from the pulse sensor 91 to the base device 17.

(0098)

This embodiment example provides the same effect as the above-described Embodiment Example 1.

(EMBODIMENT EXAMPLE 5)

(0099)

Next, Embodiment Example 5 will be described, omitting aspects identical to the above-described Embodiment Example 1.

In this embodiment example, the S-side and B-side optical device component differs from that in the above-described Embodiment Example 1.

As shown in FIG. 15, in this embodiment example, the lens 101 of the base device B-side optical device component is concave, whereas the corresponding lens 103 of the pulse sensor S-side optical device component is convex.

(0100)

In short, the concave-convex shapes of the lens 101 of the B-side optical device component and the lens 103 of the S-side optical device component are designed to fit flush against one another.

This ensures that the pulse sensor can be mounted onto the base device without misalignment. In particular, adjacently positioning the lens 101 of the B-side optical device component and the lens 103 of the S-side optical device component in the

(16)

appropriate location eliminates the effects of noise and thereby ensures good data transmission.

(EMBODIMENT EXAMPLE 6)

(0101)

Next, Embodiment Example 6 will be described, omitting aspects identical to the above-described Embodiment Example 1.

In this embodiment example, the B-side optical device component differs from that of the above-described Embodiment Example 1.

As shown in FIG. 16, in this embodiment example, a visible light-blocking film 115 is placed between the lens 113 and the B-side PD 115 of the base device B-side optical device component 111.

(0102)

This makes it possible to block noise from visible light when sending or receiving data using infrared light.

(EMBODIMENT EXAMPLE 7)

(0103)

Next, Embodiment Example 7 will be described, omitting aspects identical to the above-described Embodiment Example 1.

In this embodiment example, the S-side and B-side optical device component differs from that of the above-described Embodiment Example 1.

As shown in FIG. 17, in this embodiment example, a flat, transparent cover 123 is placed on the surface of the pulse sensor's S-side optical device component 121 (on the right in the drawing), and a lens 127 is placed between the cover 123 and the S-side infrared LED 125.

(0104)

Additionally, a flat, transparent cover 131 is placed on the surface of the base device's B-side optical device component 129 (on the left in the drawing), and a lens 135 is placed between the cover 131 and the B-side infrared LED 133.

(0105)

Although here a visible light-blocking film 139 is placed between the cover 131 and the B-side PD 137, it is acceptable to instead place the visible light-blocking film on the covers 123, 131, or to use covers 123, 131 that themselves have the ability to block visible light.

(0106)

Consequently, this makes it possible to block noise from visible light when transmitting or receiving data using infrared light. Another advantage is that, because the surface of the covers 123, 131 is flat, the surface is less prone to scratches than when the lens protrudes.

(EMBODIMENT EXAMPLE 8)

(0107)

Next, Embodiment Example 8 will be described, omitting aspects identical to the above-described Embodiment Example 1.

In this embodiment example, the S-side and B-side optical device component differs from that of the above-described Embodiment Example 1.

As shown in FIG. 18, in this embodiment example, the cover 141 of the base device's B-side optical device component is concave, and the opposing cover 143 of the pulse sensor's S-side optical device component is convex.

(0108)

In short, the concave-convex shapes of the cover 141 of the B-side optical device component and the cover 143 of the S-side optical device component are designed to fit flush against one another.

This ensures that the pulse sensor can be mounted onto the base device without misalignment. In particular, adjacently positioning the cover 141 of the B-side optical device component and the cover 143 of the S-side optical device component in the appropriate location eliminates the effects of noise and thereby ensures good data transmission.

(EMBODIMENT EXAMPLE 9)

(0109)

Next, Embodiment Example 9 will be described, omitting aspects identical to the above-described Embodiment Example 1.

In this embodiment example, the S-side and B-side optical device component differs from that of the above-described Embodiment Example 1.

As shown in FIG. 19, in this embodiment example, a pair of B-side PD 155, 157 are placed on the B-side optical device component 153 of the base device 151.

(0110)

(17)

In short, one B-side PD 155 is positioned opposite the S-side infrared LED 163 of the S-side optical device component 161 of the pulse sensor 159, while the other B-side PD 157 is positioned opposite the S-side green LED 165.

(0111)

Consequently, in this embodiment example, the presence of two pairs of light-emitting and light-receiving elements makes it possible to efficiently transmit information.

Note that the accuracy of data can be increased by transmitting and receiving a checksum signal using, for example, the S-side green LED 165 and the other B-side PD 157.

(EMBODIMENT EXAMPLE 10)

(0112)

Next, Embodiment Example 10 will be described, omitting aspects identical to the above-described Embodiment Example 1.

In this embodiment example, the manner in which the pulse sensor is mounted onto the base device differs from that in the above-described Embodiment Example 1.

As shown in FIG. 20, in this embodiment example, a recessed portion 173 is provided on the flat base device 171 so that the pulse sensor 175 can be placed level in this recessed portion 173.

(0113)

In this case, information is transmitted and received between a B-side optical device component 177 housed within the recessed portion 173 and an S-side optical device component 179 located on the underside of the pulse sensor 175.

(EMBODIMENT EXAMPLE 11)

(0114)

Next, Embodiment Example 11 will be described, omitting aspects identical to the above-described Embodiment Example 1.

In this embodiment example, the manner in which the pulse sensor is mounted onto the base device differs from that in the above-described Embodiment Example 1.

As shown in FIG. 21, in this embodiment example, the base device 18 is comprised of a disc-shaped basal component 183 with an angled top face and a cylindrical upright component 185 standing upright from the top of the basal component 183.

(0115)

At the base of the upright component 185 on the top face of the basal component 183, a basal fitting recess 189 is provided to fit the pulse sensor unit 187.

Furthermore, the aforesaid basal fitting recess 189 is tilted slightly towards the upright component 185, and its depth is set such that, when the wristband 191 is fitted around the upright component 185, the wristband 191 will not become kinked in the vertical direction.

(0116)

Consequently, when the wristband 191 is fitted around the upright component 185 and the pulse sensor unit 187 is fitted into the basal fitting recess 189, the S-side and B-side optical device components (not shown in the drawing) will be positioned in such a way as to maintain the proper distance at all times.

(0117)

It goes without saying that the present invention is by no means limited to the above-described embodiment examples, and may be embodied in any of various forms as long as these do not deviate from the scope of the present invention.

(1) For example, the pulse sensor may be configured to retain signals in memory after they have been obtained by measurement, and transmit this data to the base device. Additionally, the base device need not be connected to a PC as long as the base device is furnished with the functionality that would otherwise be performed by a PC.

(0118)

(2) Additionally, data may be transmitted using any kind of LED, not limited to infrared LED.

(BRIEF DESCRIPTION OF THE DRAWINGS)

(0119)

(FIG. 1) Perspective view showing the pulse sensor in Embodiment Example 1.

(FIG. 2) Diagram showing how the pulse sensor in Embodiment Example 1 measures pulse.

(FIG. 3) Diagram showing the configuration of the vital sign information gathering system in Embodiment Example 1.

(FIG. 4) Diagram showing how the terminals are connected in the vital sign information gathering system in Embodiment Example 1.

(FIG. 5) Diagram showing how the pulse sensor in Embodiment Example 1 is mounted onto the base device.

(18)

(FIG. 6) Diagram showing how the pulse sensor equipped with a band in Embodiment Example 1 is mounted onto the base device.

(FIG. 7) Block diagram showing the electrical configuration of the vital sign information gathering system in Embodiment Example 1.

(FIG. 8) Flowchart showing the processing of the pulse sensor in Embodiment Example 1.

(FIG. 9) Flowchart showing the processing of the pulse sensor in Embodiment Example 2.

(FIG. 10) Diagram showing the configuration of the pulse sensor in Embodiment Example 3.

(FIG. 11) Flowchart showing the main processing of the pulse sensor in Embodiment Example 3.

(FIG. 12) Flowchart showing the standby mode processing of the pulse sensor in Embodiment Example 3.

(FIG. 13) Flowchart showing the main processing of the pulse sensor in Embodiment Example 4.

(FIG. 14) Flowchart showing the standby mode processing of the pulse sensor in Embodiment Example 4.

(FIG. 15) Diagram showing the pulse sensor and base device optical device component in Embodiment Example 5.

(FIG. 16) Diagram showing the pulse sensor and base device optical device component in Embodiment Example 6.

(FIG. 17) Diagram showing the pulse sensor and base device optical device component in Embodiment Example 7.

(FIG. 18) Diagram showing the pulse sensor and base device optical device component in Embodiment Example 8.

(FIG. 19) Diagram showing the configuration of the vital sign information gathering system in Embodiment Example 9.

(FIG. 20) Diagram showing the configuration of the vital sign information gathering system in Embodiment Example 10.

(FIG. 21) Diagram showing the configuration of the vital sign information gathering system in Embodiment Example 11.

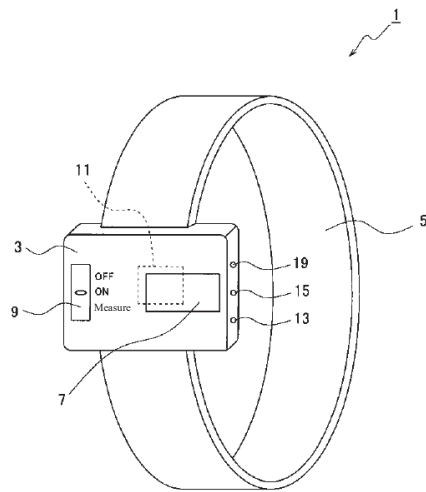
(DESCRIPTION OF REFERENCES)

(0120)

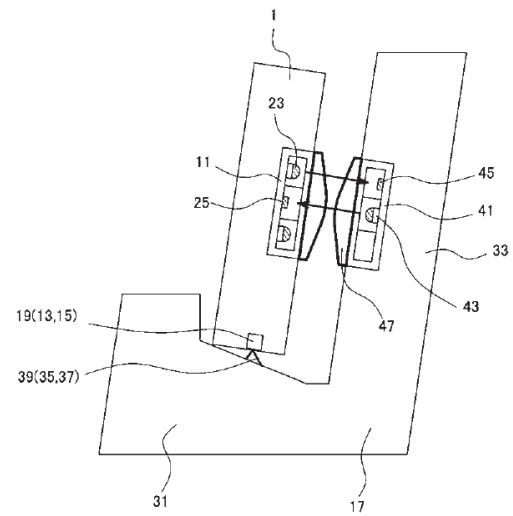
| | |
|-------------------------|---------------------------------|
| 1, 91, 159, 175: | Pulse sensor |
| 17, 151, 171, 181: | Base device |
| 21, 165: | S-side green LED |
| 23, 125, 163: | S-side infrared LED |
| 25: | S-side PD |
| 43, 133: | B-side infrared LED |
| 45, 115, 137, 155, 157: | B-side PD |
| 11, 121, 161, 179: | S-side optical device component |
| 41, 111, 129, 153, 177: | B-side optical device component |
| 31, 183: | Basal component |
| 33, 185 | Upright component |
| 19: | S-side contact-sensing terminal |
| 39: | B-side contact-sensing terminal |

(19)

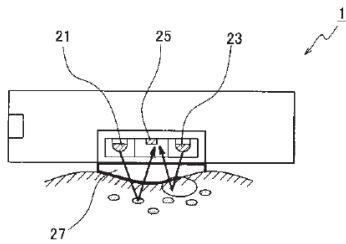
(FIG. 1)



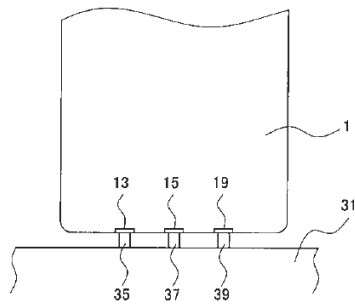
(FIG. 3)



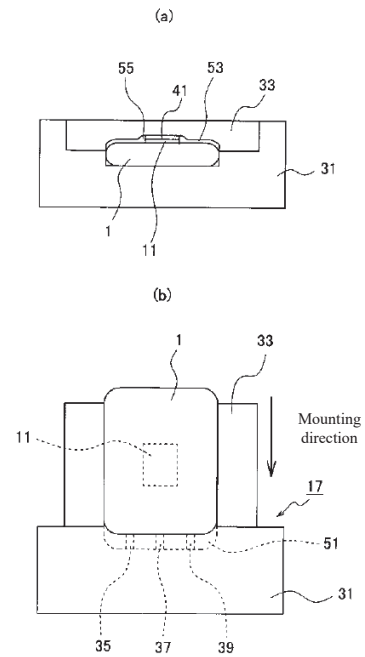
(FIG. 2)



(FIG. 4)

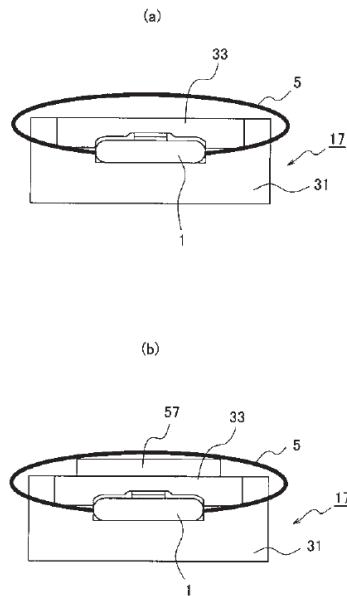


(FIG. 5)

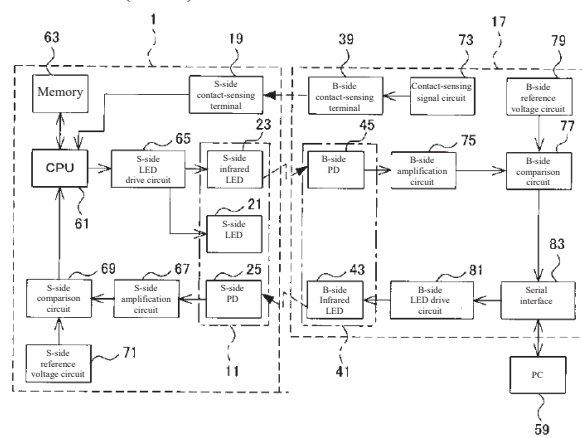


(20)

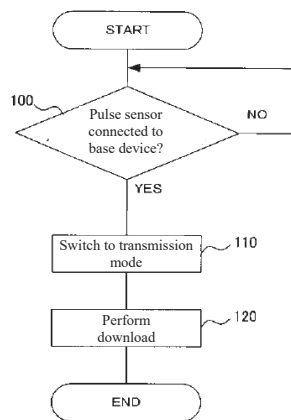
(FIG. 6)



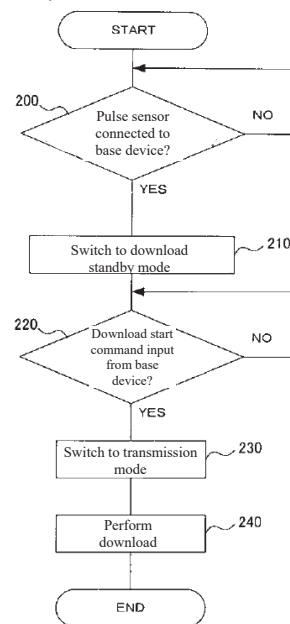
(FIG. 7)



(FIG. 8)

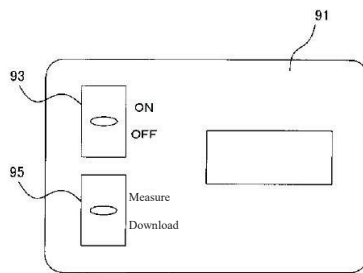


(FIG. 9)

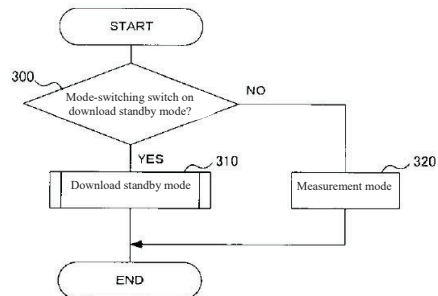


(21)

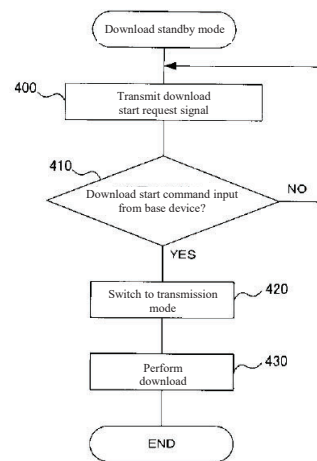
(FIG. 10)



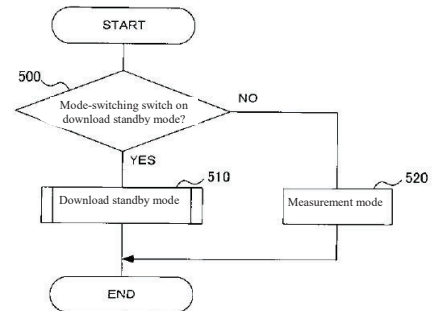
(FIG. 11)



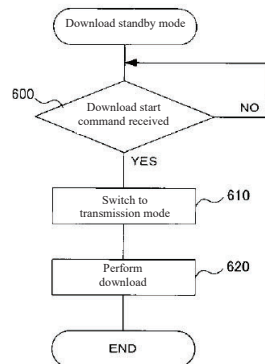
(FIG. 12)



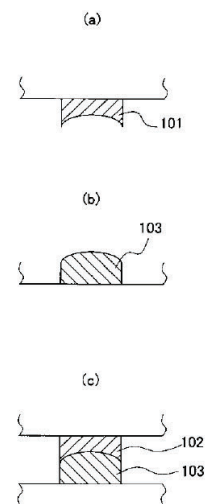
(FIG. 13)



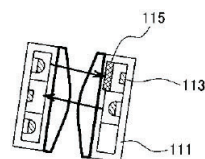
(FIG. 14)



(FIG. 15)

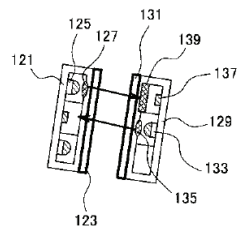


(FIG. 16)

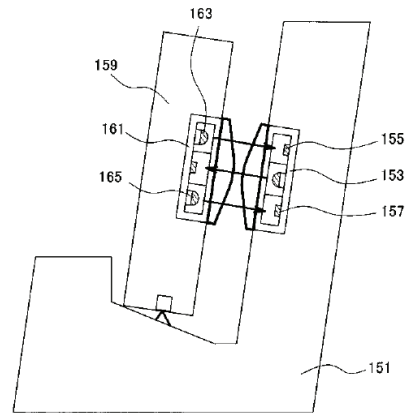


(22)

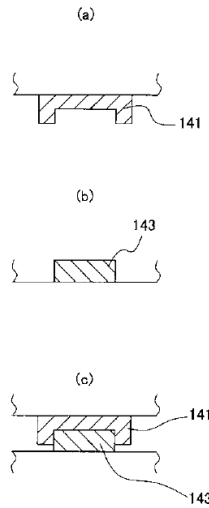
(FIG. 17)



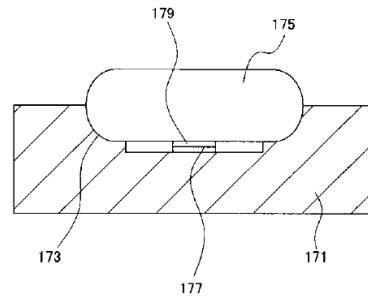
(FIG. 19)



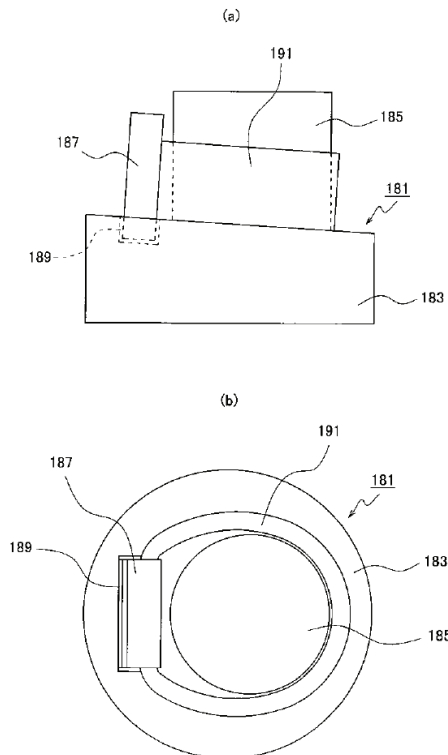
(FIG. 18)



(FIG. 20)



(FIG. 21)



(23)

Continued from the front page

(72) Inventor TOSHIYUKI MORISHITA
% Denso Corporation, 1 Showa-cho 1-chome, Kariya-shi, Aichi-ken
F terms (reference) 4C017 AA09 AB02 AB08 AC26 BB12 BC11

I, Benjamin Ettinger, hereby certify that I am competent to translate from Japanese to English and that the attached translation is, to the best of my knowledge and belief, a true and accurate translation of the following documents from Japanese to English:

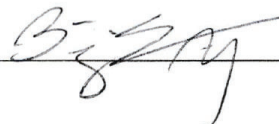
JP 2006-296564 (“Inokawa”)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Benjamin Ettinger
Printed Name

1933 East 41st Ave #413, Vancouver, BC V5P 4Y4, Canada
Address

778-386-0558
Phone



Signature



US 20010056243A1

(19) **United States**(12) **Patent Application Publication** (10) **Pub. No.: US 2001/0056243 A1****Ohsaki et al.**(43) **Pub. Date: Dec. 27, 2001**(54) **WRISTWATCH-TYPE HUMAN PULSE WAVE
SENSOR ATTACHED ON BACK SIDE OF
USER'S WRIST****Publication Classification**(51) **Int. Cl.⁷ A61B 5/02**(52) **U.S. Cl. 600/503; 600/500**(76) **Inventors: Rie Ohsaki, Anjo-city (JP); Teiyuu
Kimura, Nagoya-city (JP); Naoki
Fukaya, Obu-city (JP)**

Correspondence Address:
LAW OFFICE OF DAVID G POSZ
2000 L STREET, N.W.
SUITE 200
WASHINGTON, DC 20036 (US)

(21) **Appl. No.: 09/852,698**(22) **Filed: May 11, 2001**(30) **Foreign Application Priority Data**

Jun. 14, 2000 (JP) 2000-177999

(57) **ABSTRACT**

A pulse wave sensor includes a detecting element and a sensor body. The pulse wave sensor is worn on the back side of a user's wrist corresponding to the back of the user's hand. The detecting element includes a translucent member on its top, and the translucent member has a convex surface. The detecting element is attached on the back side of the user's wrist by a dedicated belt so that the convex surface of the translucent member is in intimate contact with the surface of the user's skin. The sensor body is attached on the back side of the user's wrist by another dedicated belt so that it is arranged on the detecting element. A cushion is arranged between the sensor body and the detecting element. The pulse wave sensor can stably detect the pulse wave without being affected by the movement of the user's wrist.

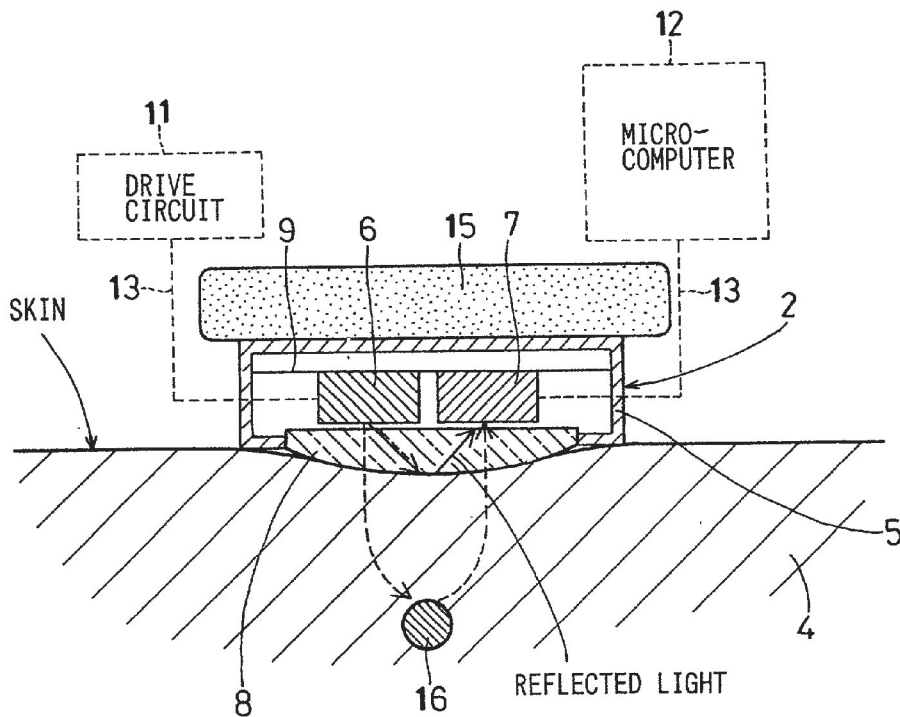


FIG. 1

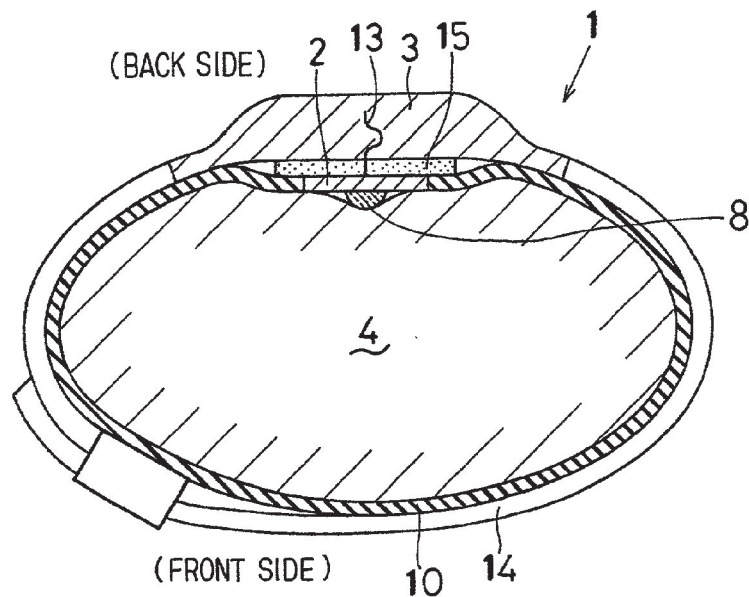


FIG. 2

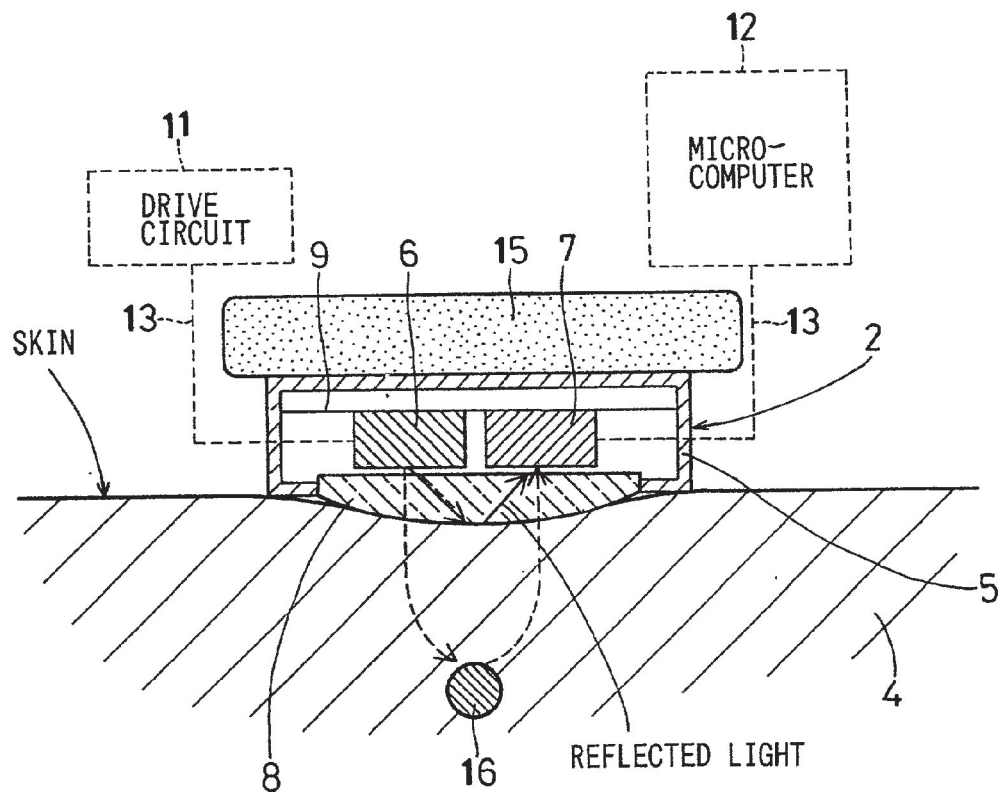


FIG. 3A

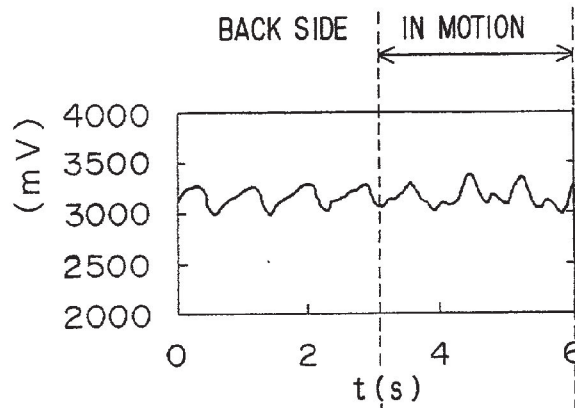


FIG. 3B

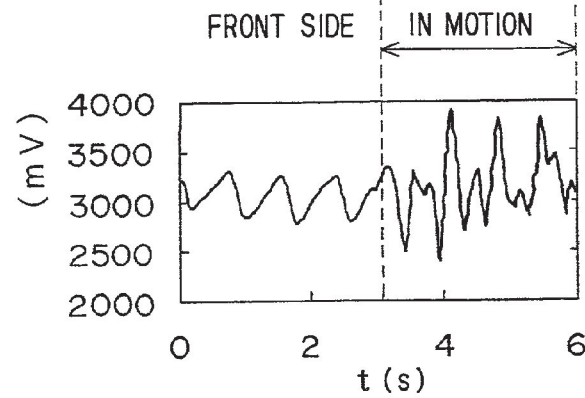


FIG. 4A

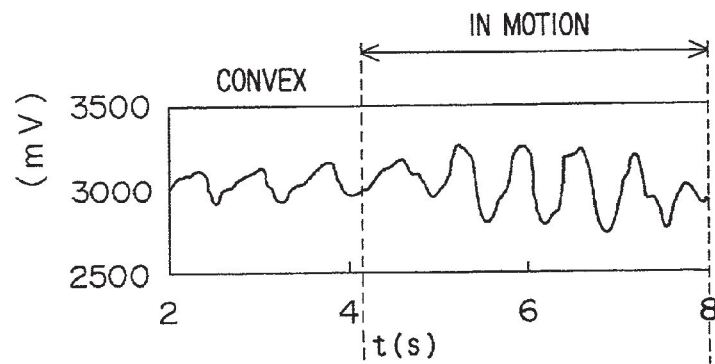
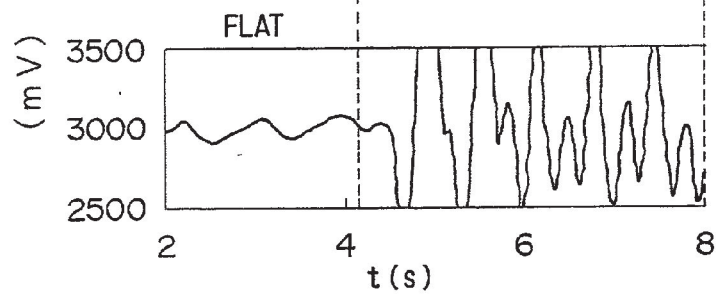


FIG. 4B



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WRISTWATCH-TYPE HUMAN PULSE WAVE SENSOR ATTACHED ON BACK SIDE OF USER'S WRIST

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application is based on and incorporates herein by reference Japanese Patent Application No.2000-177999 filed on Jun. 14, 2000.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates to an optical sensor for detecting the pulse wave of a human body.

[0004] 2. Related Art

[0005] JP-A-11-70087 proposes a wristwatch-type device for detecting the pulse wave of a human body. This detecting device is worn on the user's wrist. The device includes a detecting element for detecting a pulse wave and a sensor body including a display. The detecting element is fixed on the front side of the user's wrist corresponding to the palm of the user's hand by a band attached to the sensor body. The information of pulse wave detected by the detecting element is displayed on the display of the sensor body fixed on the back side of the user's wrist.

[0006] The two bones (the radius and the ulna) pass through the front side of the user's wrist. Therefore the detecting element has a tendency to slip off the detection position of the user's wrist, since the skin surface of the front side of the user's wrist greatly moves as the user's wrist moves. Furthermore, the user feels uncomfortable since the radius and the ulna are pressed. As a result, the user further moves his/her wrist unconsciously and it becomes further difficult to detect the pulse wave stably.

SUMMARY OF THE INVENTION

[0007] The present invention overcomes the above drawbacks, and has an object to provide a human pulse wave sensor which is capable of detecting the pulse wave of a human body stably and has high detection probability.

[0008] The pulse wave sensor according to the present invention includes a detecting element and a sensor body. The pulse wave sensor is worn on the back side of the user's wrist corresponding to the back of the user's hand for detecting the pulse wave of the user. The detecting element includes a light emitting element and a light receiving element. The sensor body is connected to the detecting element by a signal line.

[0009] Preferably, a translucent member is arranged on the light emitting element and the light receiving element. The translucent member has a convex surface. The detecting element is attached on the back side of the user's wrist by a dedicated belt so that the convex surface of the translucent member is in intimate contact with the surface of the user's skin. The light emitting element and the light receiving element are arranged in the longitudinal direction of the user's arm. The sensor body is attached on the back side of the user's wrist by a dedicated belt other than the belt of the

detecting element so that it is arranged on the detecting element. A cushion is arranged between the sensor body and the detecting element.

[0010] According to this construction, the user does not feel uncomfortable when the pulse wave sensor is worn on the user's wrist. Furthermore the detecting element is fixed on the user's wrist without slipping off the detection position of the user's wrist, even if the user is in motion. Accordingly the pulse wave sensor can stably detect the pulse wave of the user.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The above and other objects, features and advantages of the present invention will become more apparent from the following detailed description made with reference to the accompanying drawings. In the drawings:

[0012] FIG. 1 is a cross-sectional view of a pulse wave sensor attached on the user's wrist;

[0013] FIG. 2 is a schematic diagram of a mechanism for detecting a pulse wave;

[0014] FIGS. 3A and 3B are graphs of the pulse wave detected by a pulse wave sensor attached on the back side of the user's wrist and the pulse wave detected by a pulse wave sensor attached on the front side of the user's wrist, respectively; and

[0015] FIGS. 4A and 4B are graphs of the pulse wave detected by a pulse wave sensor including a convex detecting surface and the pulse wave detected by a pulse wave sensor including a flat detecting surface, respectively.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0016] Referring to FIG. 1, a pulse wave sensor 1 includes a detecting element 2 and a sensor body 3. The pulse wave sensor 1 is worn on the back side of the user's wrist 4 corresponding to the back of the user's hand in the similar manner as a wristwatch is normally worn. This sensor 1 is used for detecting the pulse wave of the user's body for a medical diagnosis, a physical check up, and the like.

[0017] Referring to FIG. 2, the detecting element 2 comprises a package 5, a light emitting element 6 (e.g., LED), a light receiving element 7 (e.g., PD), and a translucent board 8. The package 5 has an opening and includes a circuit board 9 therein. The light emitting element 6 and light receiving element 7 are included in the package 5 and arranged on the circuit board 9. The translucent board 8 is a glass board which is transparent to light, and attached to the opening of the package 5. A convex surface is formed on the top of the translucent board 8 as shown in FIG. 2.

[0018] The detecting element 2 is fixed on the user's wrist 4 by a dedicated belt 10 attached to the detecting element 2 as shown in FIG. 1. The belt 10 may be made from elastic material so that regular pressure is applied to the user's wrist 4. In this case, it is prevented that light reflected by the surface of the skin or disturbance light from the outside penetrates the translucent board 8, since the surface of the translucent board 8 is in intimate contact with the surface of the user's skin. However the user feels uncomfortable if the pressure applied to the user's wrist 4 is too high. Therefore it is desirable that the pressure applied to the user's wrist 4 is limited to 5-15 mmHg.

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[0019] The light emitting element 6 and the light receiving element 7 are arranged side by side as shown in FIG. 2. Accordingly the length of the detecting element 2 from the right side to the left side in FIG. 2 is longer than the length from the upper side to the lower side. If the detecting element 2 is arranged so that its longitudinal direction (from the right side to the left side in FIG. 2) agrees with the circumferential direction of the user's wrist 4, it has a tendency to slip off. Therefore it is desirable that the detecting element 2 is arranged so that its longitudinal direction agrees with the longitudinal direction of the user's arm. The dedicated belt 10 is attached to the detecting element 2 so that it can fix the detecting element 2 on the user's wrist 4 in this way.

[0020] The sensor body 3 is connected to the detecting element 2 by a signal line 13, and includes, as shown in FIG. 2, a drive circuit 11, a microcomputer 12, and a monitor display (not shown). The drive circuit 11 drives the light emitting element 6 to emit light toward the wrist 4. The microcomputer 12 calculates the pulse rate from the reflected light received by the detecting element 2. This reflected light varies with the user's pulsation. The monitor display shows the calculated pulse rate and the like.

[0021] The sensor body 3 is arranged on the top of the detecting element 2, and fixed on the user's wrist 4 by a dedicated belt 14 attached to the sensor body 3. A cushion 15 such as a sponge or a gel is inserted between the detecting element 2 and the sensor body 3 so that the detecting element 2 does not directly contact the sensor body 3.

[0022] The pulse wave sensor 1 detects the pulse wave of the user's body as follows. The light emitting element 6 emits light toward the user's wrist 4, a portion of the emitted light penetrates the capillary arteriole 16 in the inside of the user's wrist 4 and is absorbed by the haemoglobin in the blood. The rest of the emitted light is reflected and scattered by the capillary arteriole 16, and partly reaches the light emitting element 7. As the amount of the haemoglobin in the blood varies in waves due to the pulsation of the user's blood, the amount of the light absorbed by the haemoglobin also varies in waves. As a result, the amount of the light which is reflected by the capillary arteriole 16 and reaches the light receiving element 7 varies in waves. This variation in the amount of the light received by the light receiving element 7 is detected as the pulse wave information.

[0023] If the detecting element 2 is arranged on the front side of the user's wrist 4, the amount of the light received by the light receiving element 7 is larger. That is, the intensity of the signal received by the light receiving element 7 is higher. However, the detecting element 2 has a tendency to slip off the detecting position of the user's wrist 4 as the user moves his/her wrist, and therefore the intensity of the light received by the light receiving element 7 largely varies depending on the shift amount of the detecting element 2. As shown in FIG. 3B, in the case that the detecting element 2 is arranged on the front side of the user's wrist 4, the pulse wave can be detected well if the user is at rest. However, when the user is in motion, the detected pulse wave is adversely affected by the movement of the user's wrist 4.

[0024] In contrast to this, if the detecting element 2 is arranged on the back side of the user's wrist 4, the user will not move his/her wrist unconsciously since the radius and the ulna inside the user's wrist 4 are not pressed and

consequently the user does not feel so uncomfortable. Further, the detecting element 2 will not shift so widely even if the user's wrist moves. Therefore the detecting element 2 is stably fixed to the detecting position of the user's wrist 4. As a result, the pulse wave is detected stably without being affected by the movement of the user's wrist 4 as shown in FIG. 3A.

[0025] The detecting element 2 is arranged on the user's wrist 4 so that the convex surface of the translucent board 8 is in intimate contact with the surface of the user's skin. Thereby it is prevented that the detecting element 2 slips off the detecting position of the user's wrist 4. If the translucent board 8 has a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist 4 as shown in FIG. 4B. However, in the case that the translucent board 8 has a convex surface like the present embodiment, the variation of the amount of the reflected light which is emitted from the light emitting element 6 and reaches the light receiving element 7 by being reflected by the surface of the user's skin is suppressed. It is also prevented that noise such as disturbance light from the outside penetrates the translucent board 8. Therefore the pulse wave can be detected without being affected by the movement of the user's wrist 4 as shown in FIG. 4A.

[0026] The detecting element 2 and the sensor body 3 is attached to the user's wrist 4 by the dedicated belts 10 and 14, respectively. That is, the detecting element 2 and the sensor body 3 are allowed to move relatively. Further the cushion 15 is arranged between the detecting element 2 and the sensor body 3. Therefore, if force is applied to the sensor body 3 or the sensor body 3 moves, the force applied to the sensor body 3 or the movement of the sensor body 3 cannot be transmitted to the detecting element 2 easily.

[0027] Accordingly the detecting element 2 is stably fixed to the user's wrist 4. As a result, the pulse wave sensor can detect the pulse wave at a high S/N ratio, that is, it can provide high detection probability, not only when the user is at rest but also when the user is taking light exercise.

[0028] Modifications

[0029] In the above embodiment, the sensor body 3 need not include the microcomputer 12 if it includes a transmitter instead. In this case, the pulse wave information detected by the detecting element 2 is transmitted to a receiver by the transmitter. The sensor body 3 can be downsized and light in weight in this case and consequently the force applied to the sensor body 3 or the movement of the sensor body 3 cannot be transmitted to the detecting element 2 easily.

[0030] In the above embodiment, the detecting element 2 and the sensor body 3 may be worn on the back side of the user's forearm.

What is claimed is:

1. A pulse wave sensor for detecting a pulse wave of a human body comprising:

a detecting element including a light emitting element and a light receiving element; and

a sensor body including a circuit connected to the detecting element via a signal line,

wherein the detecting element is constructed to be worn on a back side of a user's wrist or a user's forearm.

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2. A pulse wave sensor as set forth in claim 1, wherein:
the detecting element includes a translucent member
which is transparent to light and arranged on the light
emitting element and the light receiving element;
the translucent member has a convex surface; and
the translucent member is arranged on the back side of the
user's wrist or the user's forearm so that the convex
surface of the translucent member is in intimate contact
with a surface of the user's skin.

3. A pulse wave sensor for detecting a pulse wave of a
human body comprising:
a detecting element including a light emitting element and
a light receiving element; and
a sensor body including a circuit connected to the detect-
ing element via a signal line,
wherein the detecting element is constructed to be worn
on a user's wrist or a user's forearm,
the pulse wave sensor further comprising:
a first belt for fixing the detecting element to the user's
wrist or the user's forearm; and
a second belt for fixing the sensor body to the user's wrist
or the user's forearm.

4. A pulse wave sensor for detecting a pulse wave of a
human body comprising:
a detecting element including a light emitting element and
a light receiving element; and
a sensor body including a circuit connected to the detect-
ing element via a signal line,
wherein the detecting element is constructed to be worn
on a user's wrist or a user's forearm,
wherein the sensor body is arranged on the detecting
element, and

wherein a cushion is arranged between the detecting
element and the sensor body.

5. A pulse wave sensor for detecting a pulse wave of a
human body comprising:
a detecting element including a light emitting element and
a light receiving element; and
a sensor body including a circuit connected to the detect-
ing element via a signal line,
wherein the detecting element is constructed to be worn
on a user's wrist or a user's forearm,
wherein the light emitting element and the light receiving
element are arranged side by side in a longitudinal
direction of the user's arm.

6. A pulse wave sensor as set forth in claim 5, wherein:
the detecting element includes a translucent member
which is transparent to light and arranged on the light
emitting element and the light receiving element;
the translucent member has a convex surface; and
the translucent member is arranged on the user's wrist or
the user's forearm so that the convex surface of the
translucent member is in intimate contact with a surface
of the user's skin.

7. A pulse wave sensor as set forth in claim 6 further
comprising:
a first belt for fixing the detecting element to the user's
wrist or the user's forearm; and
a second belt for fixing the sensor body to the user's wrist
or the user's forearm.

8. A pulse wave sensor as set forth in claim 7, wherein:
the sensor body is arranged on the detecting element; and
a cushion is arranged between the detecting element and
the sensor body.

* * * * *

Design and Evaluation of a New Reflectance Pulse Oximeter Sensor

Y. MENDELSON, PhD, J. C. KENT, MS, B. L. YOCUM, BS, AND M. J. BIRLE, BS

The design and construction of a new optical reflectance sensor suitable for noninvasive monitoring of arterial hemoglobin oxygen saturation with a pulse oximeter is described. The reflectance sensor was interfaced to a Datascope ACCUSAT pulse oximeter that was specially adapted for this study to perform as a reflectance oximeter. We evaluated the reflectance sensor in a group of 10 healthy adult volunteers. SpO_2 obtained from the forehead with the reflectance pulse oximeter and SpO_2 obtained from a finger sensor that was connected to a standard ACCUSAT transmittance pulse oximeter were compared simultaneously to arterial blood samples analyzed by an IL 282 CO-Oximeter. The equation for the best fitted linear regression line between the reflectance SpO_2 and HbO_2 values obtained from the reference IL 282 CO-Oximeter in the range between 62 and 100% was: $\text{SpO}_2 (\%) = 4.78 + 0.96 (\text{IL})$; $n = 110$. The regression analysis revealed a high degree of correlation ($r = 0.98$) and a relatively small standard error of the estimate ($\text{SEE} = 1.82\%$). The mean and standard deviations for the difference between the reflectance SpO_2 and IL 282 measurements was 1.38 and 1.85%, respectively. This study demonstrates the ability to acquire accurate SpO_2 from the forehead using a reflectance sensor and a pulse oximeter.

The recent development of transmittance pulse oximeters by combining optical plethysmography with the spectrophotometric determination of hemoglobin oxygen saturation in arterial blood (SpO_2) has provided a widely used technique for monitoring hypoxemia.

With transmittance pulse oximeters, sensor application is limited to several peripheral locations where light can be readily transmitted and detected, such as the finger tips, ear lobes, and toes on adults, and the foot or palms on infants. Alternatively, skin reflectance oximetry could enable SpO_2 measurement from more centrally located parts of the body such as the forearms, chest, and forehead, which cannot be monitored using conventional transillumination techniques.

It appears that reflectance pulse oximetry may be particularly suitable for direct assessment of fetal distress resulting from hypoxia during delivery, if used in addition to monitoring fetal heart rate by a scalp ECG electrode. Another suggested application of noninvasive reflectance pulse oximetry is for monitoring SpO_2 in the external carotid artery through a sensor applied to the skin near the superficial temporal artery.¹

In this article we describe the design and construction

of an optical reflectance sensor suitable for noninvasive monitoring of SpO_2 with a pulse oximeter. The experimental evaluation of the new sensor and verification that SpO_2 obtained with the reflectance sensor compare favorably with: (a) SpO_2 measured simultaneously by a finger sensor connected to a standard transmittance pulse oximeter, and (b) HbO_2 measured by the IL 282 CO-Oximeter from samples of arterial blood in a group of 10 healthy adult volunteers is presented.

PULSE OXIMETRY

The principle of pulse oximetry was proposed by Aoyagi *et al.*² and further developed by Yoshiya *et al.*³ This unique approach is based on the change in light absorption by tissue. The change is caused primarily by arterial blood pulsation. The pulsating arterioles in a vascular bed, by expanding and relaxing, modulate the amount of light absorbed by the tissue and thus produce a characteristic photoplethysmographic waveform. The changes in light absorption are used to measure SpO_2 noninvasively.

Initial attempts to develop a noninvasive oximeter that can measure oxygen saturation by analyzing the absolute light intensity that is diffusely reflected from the skin were only partially successful, mainly because of limited accuracy associated with variations in tissue attenuation and differences in skin pigmentation. Recently, we showed that accurate SpO_2 measurements can be made utilizing a reflectance sensor and the concept of pulse oximetry.^{4,5} We found that SpO_2 can be calculated from the ratio of the reflected red and infrared photoplethysmograms based on a normalization in which the pulsatile (ac) component of the red and infrared photoplethysmograms is divided by the respective nonpulsatile (dc) component. The conversion of the red/infrared ratios to SpO_2 is performed by an empirical calibration of the oximeter. This process is performed by comparing the red/infrared ratios measured by the pulse oximeter with blood HbO_2 values obtained from an *in vitro* oximeter.

The excursions of photoplethysmographic signals detected by reflectance and transmittance sensors when placed on the forehead and finger, respectively, are inversely related to changes in arterial blood pulsations. Although the amplitude of the pulsatile component of the two waveforms is different, the shapes of the pho-

From the Worcester Polytechnic Institute, Biomedical Engineering Program, Worcester, MA 01609.

Address correspondence and requests for reprints to Yitzhak Mendelson, PhD, Biomedical Engineering Program, Worcester Polytechnic Institute, 100 Institute Rd., Worcester, MA 01609.

toplethysmograms are virtually identical, as illustrated in Figure 1.

SENSOR DESIGN

The basic optical sensor of a pulse oximeter consists of a red and an infrared light emitting diode (LED) and a suitable photodetector. In a transmittance pulse oximeter sensor, the LEDs and the photodetector are mounted in opposition, whereas in a reflectance sensor, the LEDs and the photodetector are mounted side by side. The wavelength of the red LED is typically chosen from regions of the spectra where the absorption coefficient of Hb and HbO₂ are markedly different (*e.g.*, 660 nm). The infrared wavelength, on the other hand, is typically chosen from the spectral region where the difference in absorption coefficients of Hb and HbO₂ is relatively small (*e.g.*, 930 nm). The spectral response of the photodetector must overlap the emission spectra of the red and infrared LEDs.

Practically, the major limitation in reflection pulse oximetry is the comparatively low-level photoplethysmograms typically recorded from low-density, vascular areas of the skin. The feasibility of reflection pulse oximetry, therefore, is essentially dependent on the ability to design a sensor that can detect sufficiently strong reflection photoplethysmographic signals from various locations on the body.

The light from the LEDs in the reflectance sensor is diffused by the skin in all directions. This suggests that to detect most of the backscattered radiation from the skin, the photodetector must be able to detect light from an area concentric with the LEDs. The intensity of the backscattered light decreases in direct proportion to the square of the distance between the photodetector and the LEDs; thus the photodetector should be mounted close to the LEDs. We found experimentally that a separation of 4–5 mm between the LEDs and photodetector provides the best sensitivity in terms of detecting ade-

quately large pulsatile components. We also found that when multiple photodetectors are arranged at equal distances around the LEDs, the total amount of backscattered light that can be detected by the reflectance sensor is directly proportional to the number of photodetectors.

The optical reflectance sensor used in this study consists of two red (peak emission wavelength: 660 nm) and two infrared (peak emission wavelength: 930 nm) LED chips (dimensions: 0.3 × 0.3 mm), and six silicon photodiodes (active area: 2.74 × 2.74 mm) arranged symmetrically in a hexagonal configuration as shown in Figure 2. To maximize the fraction of backscattered light collected by the sensor, the currents from all six photodiodes were summed. The LEDs and photodiode chips were mounted with conductive epoxy (Epo-tek H31, Epoxy Technology, Inc. Billerica, Massachusetts) on a ceramic substrate (dimensions: 13.2 × 13.2 × 0.25 mm) that was housed in a standard 24-pin (dimensions: 19 × 19 mm) microelectronic package (AIRPAX, Cambridge, Maryland), which is commonly used for packaging electronic circuits. The optical components were interconnected and wired to the package pins with 1-mil (0.0254-mm diameter) aluminum wires, by a conventional ultrasonic bonding technique. To minimize the amount of light transmission and reflection between the LEDs and the photodiodes within the sensor, a ring-shaped, optically opaque shield of black Delrin (Dupont, Wilmington, Delaware) was placed between the LEDs and the photodiode chips. The optical components were encapsulated inside the package using optically clear adhesive (NOA-63, Norland Products, Inc., New Brunswick, New Jersey). The microelectronic package was mounted inside a black Delrin housing (dimensions: 3.2-cm diameter × 1.5-cm high). The sensor can be attached to the skin by means of double-sided adhesive tape. The weight of the entire sensor assembly is approximately 11 g.

SIGNAL PROCESSING

The optical reflectance sensor was interfaced to a com-

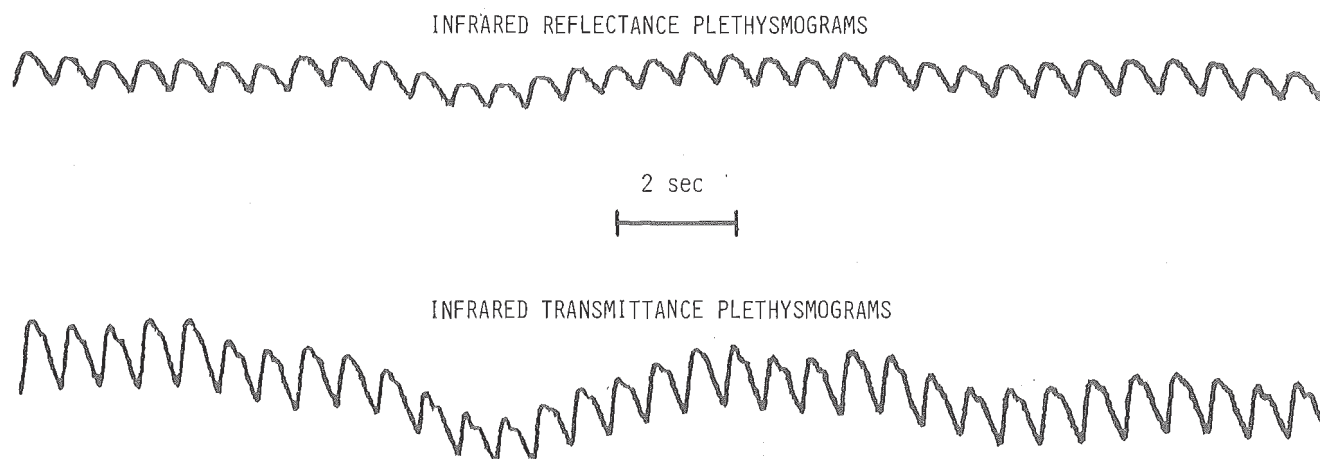


Figure 1. Relative infrared reflectance and transmittance photoplethysmograms recorded from the forehead and finger, respectively.

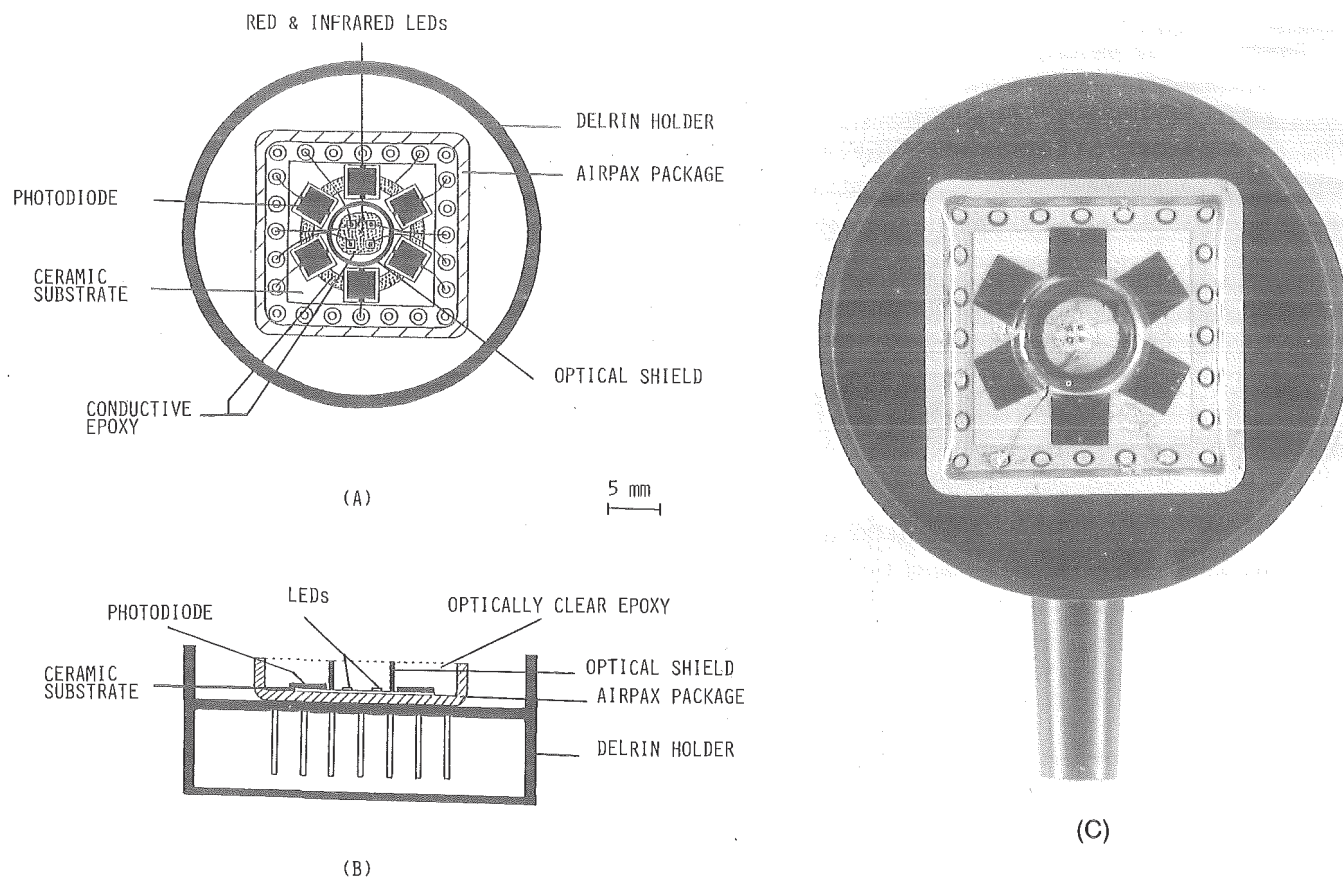


Figure 2. Diagram (A and B) and photograph (C) of the reflectance pulse oximeter sensor.

mercially available ACCUSAT (Datascope, Paramus, New Jersey) pulse oximeter.⁶ The oximeter circuitry generates separate digital pulses to energize alternately the red and infrared LEDs in the sensor. The time-multiplexed current pulses from the photodiodes, which correspond to the red and infrared light intensities reflected from the skin, are first converted by the oximeter to proportional voltage pulses. The pulses are subsequently demultiplexed into two separate channels. The red and infrared photoplethysmographic signals are then amplified and high-pass filtered to separate the ac and dc components of each photoplethysmographic waveform.

Before the study began, an ACCUSAT pulse oximeter was modified by adjusting the intensities of the red and infrared LEDs so that the dc component of each photoplethysmogram was approximately equal to the corresponding dc level obtained from transmittance photoplethysmograms as measured by a standard ACCUSAT sensor designed for a finger. The adjustment was performed while the reflectance and transmittance sensors were applied to the forehead and right index finger of a white subject breathing ambient air. No further adjustments were made throughout the study. The reflectance oximeter was adapted to provide a continuous readout of the ac and dc components of the red and infrared photoplethysmograms.

In addition to the modified ACCUSAT pulse oximeter, a second standard ACCUSAT transmittance pulse oximeter was used to measure SpO_2 with a finger sensor. SpO_2 from each of the two pulse oximeters was acquired every 2 s (0.5 Hz) using an AT&T 6300 personal computer. The conversion of the transmitted and reflected red/infrared ratios measured by each ACCUSAT pulse oximeter to SpO_2 was performed using the same internal calibration algorithms. The exact algorithm for calculating SpO_2 was unavailable.

IN VIVO EVALUATION

The purpose of this study was to evaluate the performance of the reflectance pulse oximeter sensor during progressive steady-state hypoxia in humans and to compare the values obtained with the reflectance sensor to those from an ACCUSAT transmittance pulse oximeter and from the IL CO-Oximeter detecting the HbO_2 of simultaneously drawn arterial blood samples.

Tests were performed on 10 healthy, nonsmoking, adult volunteers of different ages and skin pigmentations in compliance with the University of Massachusetts Medical Center review guidelines for humans experiments. The subject distribution was: one deeply pigmented black, two subjects of lightly pigmented Oriental descent, and

two darkly tanned and five lightly tanned whites. Subject age ranged from 22–39 years (mean \pm SD: 29.2 ± 5.6 years). Measured hematocrit was in the range of 35–44% (mean \pm SD: $40 \pm 2.65\%$). Each volunteer was informed of the complete procedure and possible risks associated with arterial cannulation and hypoxic gas breathing. Each volunteer received monetary compensation for participation in the study.

A modified Allen's test for assessing the radial and ulnar arterial blood circulation to the hand was performed on each subject prior to arterial cannulation. A Teflon cannula (22-gauge, 3.2-cm long) was inserted into the radial or ulnar artery of each subject after the subcutaneous tissue around the puncture site was anesthetized locally with a 1-ml injection of 1% lidocaine hydrochloride (Xylocaine).

All instruments warmed up for at least 30 min before the study. The transmittance sensor of the ACCUSAT pulse oximeter was attached to the index finger on the hand opposite that of the arm with the arterial cannula. The sensor of the reflectance pulse oximeter was attached to the middle of the forehead. Samples of arterial blood (approximately 1 ml/sample) were drawn into 3-ml heparinized syringes and analyzed immediately by the

Instrumentation Laboratories IL 282 CO-Oximeter (Instrumentation Laboratories, Lexington, Massachusetts). Simultaneous measurements of total hemoglobin (Hb), oxyhemoglobin (HbO_2), carboxyhemoglobin (HbCO), and methemoglobin (Hi) were obtained from each blood sample. The arterial cannula was flushed with 0.9% normal heparinized saline solution (1000 units/250 ml) between blood samplings. Care was taken to ensure that the arterial line and the blood-sampling syringes were free of air bubbles.

A standard lead I ECG and the end-tidal CO_2 were continuously monitored by a Hewlett-Packard 78345A patient monitor (Hewlett-Packard, Andover, Massachusetts). Each subject was placed in the supine position. A face mask was tightly fitted over the subject's mouth and nose, and the subject was asked to breathe spontaneously different O_2 and N_2 gas mixtures. The inspired O_2/N_2 gas was supplied by a modified Heidbrink anesthesia machine (Ohio Medical Products, Madison, Wisconsin). The breathing circuit was equipped with a CO_2 scrubber (soda lime). Inspired O_2 concentration was adjusted between 10 and 100% and was monitored continuously with an IL 408 oxygen monitor that was inserted in the inspiratory part of the breathing circuit.

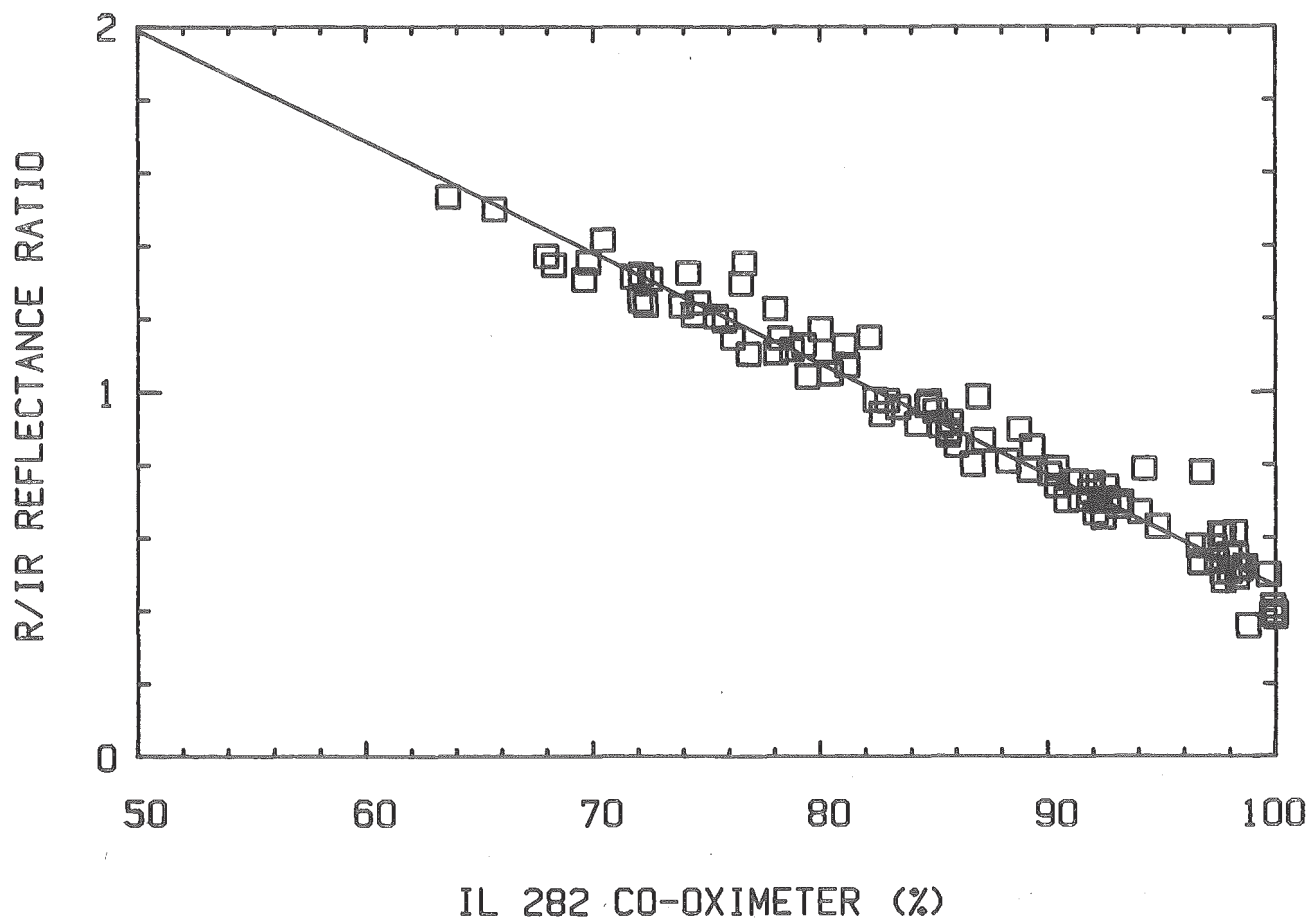


Figure 3. Comparison of the IL 282 CO-Oximeter (x-axis) and the red/infrared ratios measured by the reflectance pulse oximeter (y-axis) during progressive steady-state hypoxia in 10 subjects. $y = 3.51 - 0.030x$; $r = -0.98$; $\text{SEE} = 0.060$; $n = 110$; $p < 0.001$. The solid line represents the best fitted linear regression line.

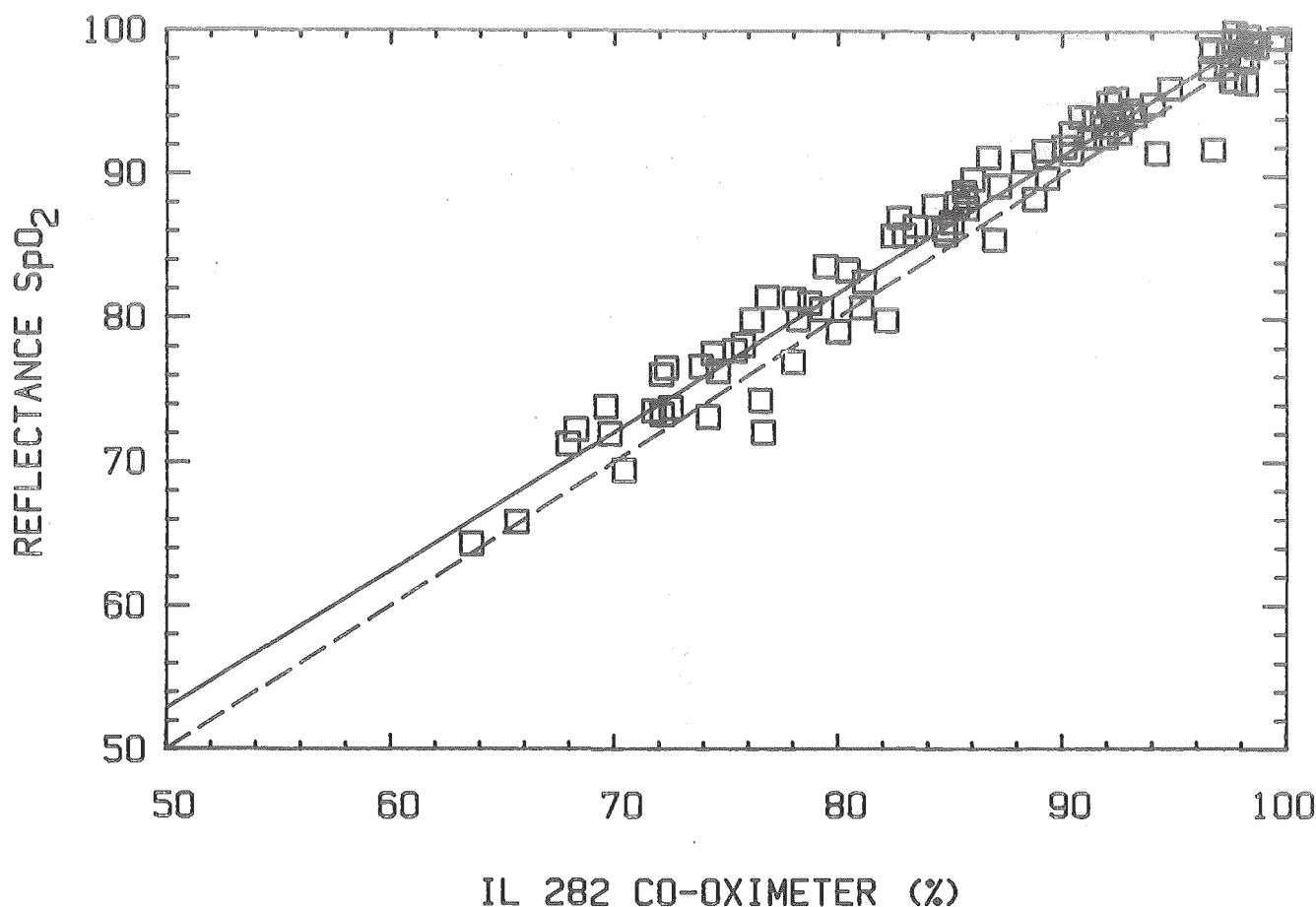


Figure 4. Comparison of SpO_2 measurements obtained from the reflectance pulse oximeter (y-axis) and the IL 282 CO-Oximeter (x-axis) during progressive steady-state hypoxia in 10 subjects. $y = 4.78 + 0.96x$; $r = 0.98$; $\text{SEE} = 1.82$; $n = 110$; $p < 0.001$. The solid line represents the best fitted linear regression line. The dashed line represents identity.

Progressive hypoxemia was gradually induced by changing the inspired fractions of O_2 and N_2 . To provide a relatively uniform distribution of SpO_2 data points, samples were recorded during both desaturation and reoxygenation. Initially, the inspired O_2 concentration was changed in step decrements, each producing approximately a 5% decrease in SpO_2 as determined from the ACCUSAT transmittance pulse oximeter display. The inspired O_2 was maintained at each level until the pulse oximeter readings were stable. When the inspired O_2 reached 10%, corresponding to a saturation of approximately 65%, the process was reversed, and the inspired O_2 was increased in a similar stepwise manner to 100%. SpO_2 from the ACCUSAT and the reflectance pulse oximeters during blood sampling was acquired every 2 s (0.5Hz), using an AT&T 6300 personal computer.

None of the subjects showed ECG abnormalities before or during the study. All subjects tolerated the procedure well, without adverse reactions.

DATA ANALYSIS

For each step change in inspired O_2 , readings from

the ACCUSAT transmittance and reflectance pulse oximeters were averaged for 10 s before and after blood sampling and compared with the corresponding HbO_2 values measured by the IL 282 CO-Oximeter. To avoid operator biases, the data from each pulse oximeter were acquired automatically by the computer and later subjected to the same statistical tests. Averaged readings for the 10 subjects were pooled and a least-squares linear regression analysis was performed. Student's t test determined the significance of each correlation; $p < 0.001$ was considered significant.

The SpO_2 displayed by two-wavelength pulse oximeters account only for the presence of HbO_2 and Hb in the blood. The presence of HbCO , Hi , or any other interfering substance in the blood is not accounted for. Therefore, the term often used to represent SpO_2 measured by pulse oximeters is functional saturation, *i.e.*, $\text{HbO}_2/(\text{Hb} + \text{HbO}_2)$. The IL 282 CO-Oximeter, on the other hand, displays the percentage of oxygenated hemoglobin expressed as a fraction of the total hemoglobin present in the blood, *i.e.*, $\text{HbO}_2/(\text{Hb} + \text{HbO}_2 + \text{HbCO} + \text{Hi})$. To compare SpO_2 measured by the pulse oximeters with corresponding readings from the IL 282

CO-Oximeter, both HbCO and Hi values from each blood sample were used to convert the IL 282 readings to functional SpO₂, according to the following relationship⁷:

$$\% \text{SpO}_2 (\text{functional}) = (\text{HbO}_2 \times 100) / (100 - \text{HbCO} - \text{Hi}).$$

RESULTS

A total of 110 pairs of data points were used in the regression analysis, which gave the estimated slopes and intercepts of the regression lines. An average of 11 blood samples was collected from each subject. Each pair of data points represents a different hypoxic level. Regression analysis of the HbO₂ values obtained from the IL 282 CO-Oximeter (x-axis) vs the normalized red/infrared ratios (y-axis) as measured by the reflectance pulse oximeter is shown in Figure 3. The equation for the best fitted linear regression line was: $y = 3.51 - 0.030x$; $r = -0.98$; $\text{SEE} = 0.060$; $p < 0.001$. A comparison of SpO₂ readings from the reflectance pulse oximeter (y-axis) and the IL 282 CO-Oximeter (x-axis) is shown in Figure 4. The equation for the best fitted linear regression line was: $y = 4.78 + 0.96x$; $r = 0.98$; $\text{SEE} = 1.82$;

$p < 0.001$. Figure 5 shows the comparison of SpO₂ values measured by the ACCUSAT reflectance pulse oximeter (y-axis) and the ACCUSAT transmittance pulse oximeter (x-axis). The linear regression equation for this comparison is: $y = 5.85 + 0.95x$; $r = 0.98$; $\text{SEE} = 2.23$; $p < 0.001$. The standard deviations of the mean differences between the reflectance oximeter SpO₂ and IL 282 HbO₂ values for four different saturation ranges are summarized in Figure 6.

DISCUSSION

Pulse oximetry has become a widely utilized medical technology, particularly in anesthesia and intensive care. Pulse oximeters offer significant monitoring advantages because of their reliability, simple operation, and the benefit of providing continuous SpO₂ monitoring.

Noninvasive monitoring of oxygen saturation based upon skin-reflectance spectrophotometry was first described by Brinkman and Zijlstra.⁸ They showed that changes in oxygen saturation can be recorded noninvasively from an optical sensor attached to the forehead. The use of light reflection instead of tissue transillumination

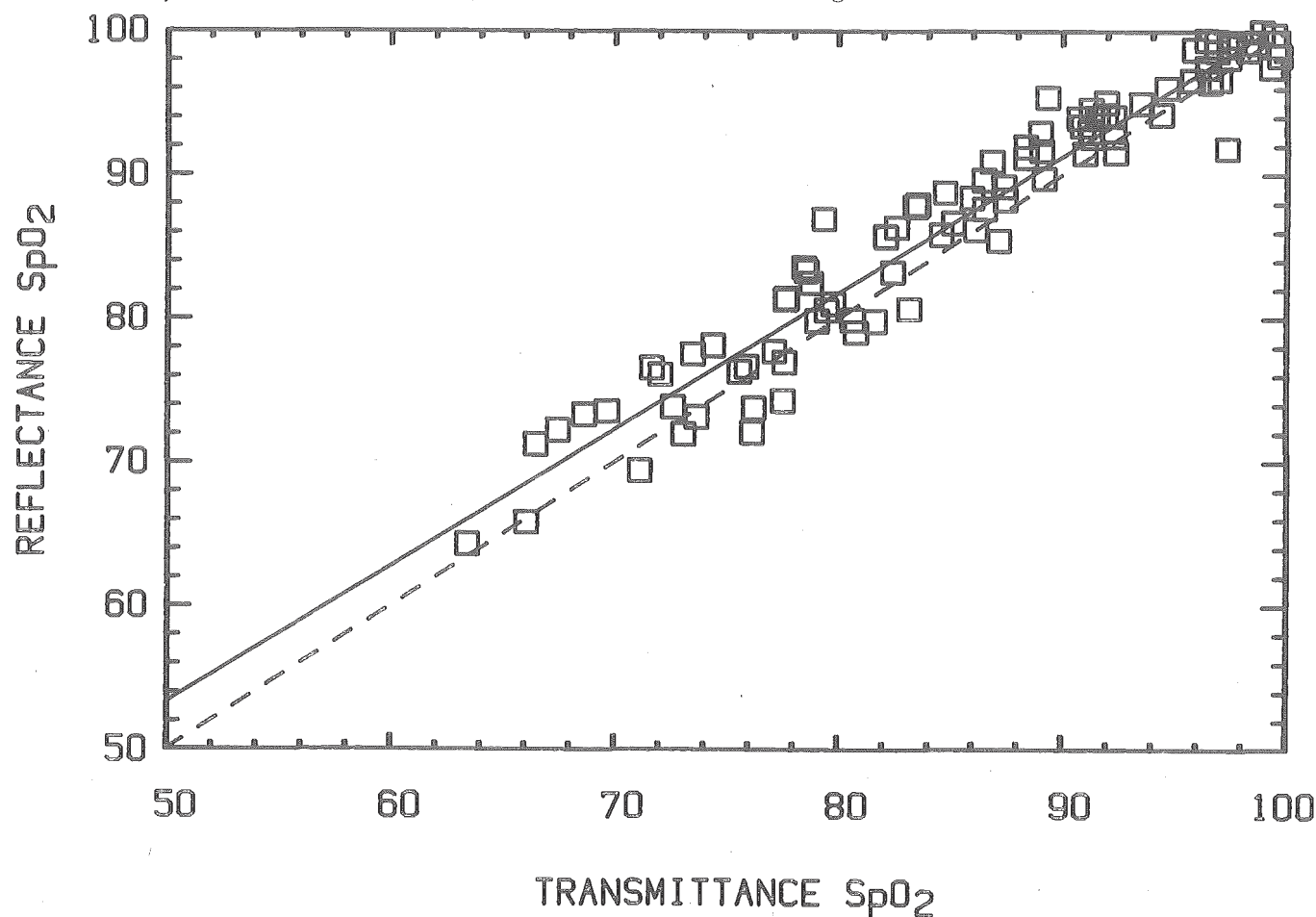


Figure 5. Comparison of SpO₂ measured by the reflectance pulse oximeter (y-axis) and the finger transmittance pulse oximeter (x-axis) during progressive steady-state hypoxia in 10 subjects. $y = 5.85 + 0.95x$; $r = 0.98$; $\text{SEE} = 2.23$; $n = 110$; $p < 0.001$. The solid line represents the best fitted linear regression line. The dashed line represents identity.

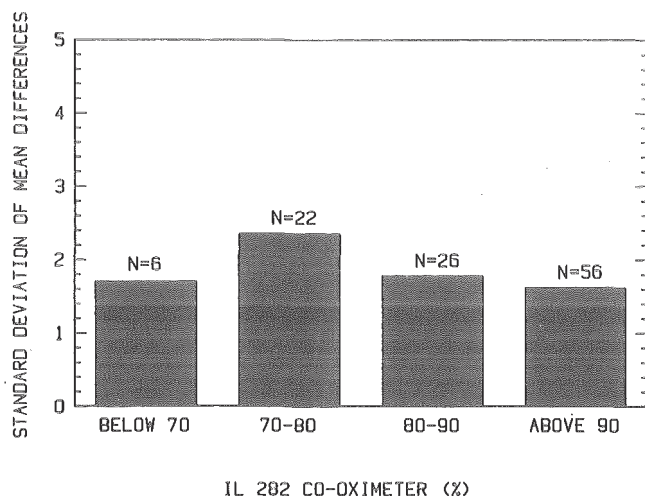


Figure 6. Standard deviations of the mean differences between the reflectance pulse oximeter and the IL 282 CO-Oximeter. N is the number of paired data points included in the statistical analysis.

nation was suggested to enable noninvasive monitoring from virtually any skin surface. More recently, Cohen and Wadsworth⁹ and Takatani¹⁰ attempted to develop a skin reflectance oximeter utilizing a similar spectrophotometric approach. In those three reflectance oximeters, oxygen saturation was calculated from the absolute light intensity diffusely reflected (backscattered) from the skin. Although these developments represent significant advancements in noninvasive oximetry, the major problems were limited accuracy, poor reproducibility, and difficulties in absolute calibration.

Available transmittance pulse oximeters can be used only on a few specific peripheral locations. The approach presented in this article demonstrates that SpO₂ can be measured from an alternate site, specifically the forehead. This technique provides a clinically acceptable alternative to presently available transmittance pulse oximeters. Although we found that reflectance photoplethysmograms can be detected from several locations on the body (*e.g.*, forearm, chest, and back), the relatively small, photoplethysmographic signals lead to practical problems when processed by the pulse oximeter. Therefore, the choice of the forehead as a site for our study was based on the fact that at this location, relatively large reflectance photoplethysmographic signals can be detected.

The relationship between the red/infrared ratios measured by the reflectance pulse oximeter and HbO₂ measured by the IL 282 CO-Oximeter produced a regression relationship similar in slope and intercept to that observed from transmittance pulse oximeters.¹¹ This suggests that SpO₂ monitoring from the forehead can be

performed successfully using a reflectance sensor connected to a standard transmittance pulse oximeter without significant modifications of hardware and software.

SUMMARY

We compared simultaneous SpO₂ from a reflectance pulse oximeter sensor attached to the forehead and from a transmittance pulse oximeter with a sensor attached to a finger with HbO₂ from arterial blood samples in a group of 10 healthy adult volunteers. A high degree of correlation was found for SpO₂ between 62 and 100%. Relative to arterial blood samples, the SEE for the reflectance pulse oximeter was 1.82%. We conclude that in situations in which a transmittance pulse oximeter cannot be used reliably, the forehead may be considered as a suitable alternative site for monitoring SpO₂ with a reflectance pulse oximeter sensor.

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A Wearable Reflectance Pulse Oximeter for Remote Physiological Monitoring

Y. Mendelson*, *Member, IEEE*, R. J. Duckworth, *Member, IEEE*, and G. Comtois, *Student Member, IEEE*

Abstract—To save life, casualty care requires that trauma injuries are accurately and expeditiously assessed in the field. This paper describes the initial bench testing of a wireless wearable pulse oximeter developed based on a small forehead mounted sensor. The battery operated device employs a lightweight optical reflectance sensor and incorporates an annular photodetector to reduce power consumption. The system also has short range wireless communication capabilities to transfer arterial oxygen saturation (SpO_2), heart rate (HR), body acceleration, and posture information to a PDA. It has the potential for use in combat casualty care, such as for remote triage, and by first responders, such as firefighters.

I. INTRODUCTION

STEADY advances in noninvasive physiological sensing, hardware miniaturization, and wireless communication are leading to the development of new wearable technologies that have broad and important implications for civilian and military applications [1]-[2]. For example, the emerging development of compact, low-power, small-size, light-weight, and unobtrusive wearable devices may facilitate remote noninvasive monitoring of vital signs from soldiers during training exercises and combat. Telemetry of physiological information via a short-range wirelessly-linked personal area network can also be useful for firefighters, hazardous material workers, mountain climbers, or emergency first-responders operating in harsh and hazardous environments. The primary goals of such a wireless mobile platform would be to keep track of an injured person's vital signs, thus readily allowing the telemetry of physiological information to medical providers, and support emergency responders in making critical and often life saving decisions in order to expedite rescue operations. Having wearable physiological monitoring could offer far-forward medics numerous advantages, including the ability to determine a casualty's condition remotely without exposing the first

responders to increased risks, quickly identifying the severity of injuries especially when the injured are greatly dispersed over large geographical terrains and often out-of-site, and continuously tracking the injured condition until they arrive safely at a medical care facility.

Several technical challenges must be overcome to address the unmet demand for long-term continuous physiological monitoring in the field. In order to design more compact sensors and improved wearable instrumentation, perhaps the most critical challenges are to develop more power efficient and low-weight devices. To become effective, these technologies must also be robust, comfortable to wear, and cost-effective. Additionally, before wearable devices can be used effectively in the field, they must become unobtrusive and should not hinder a person's mobility. Employing commercial off-the-shelf (COTS) solutions, for example finger pulse oximeters to monitor blood oxygenation and heart rate, or standard adhesive-type disposable electrodes for ECG monitoring, is not practical for many field applications because they limit mobility and can interfere with normal tasks.

A potentially attractive approach to aid emergency medical teams in remote triage operations is the use of a wearable pulse oximeter to wirelessly transmit heart rate (HR) and arterial oxygen saturation (SpO_2) to a remote location. Pulse oximetry is a widely accepted method that is used for noninvasive monitoring of SpO_2 and HR. The method is based on spectrophotometric measurements of changes in the optical absorption of deoxyhemoglobin (Hb) and oxyhemoglobin (HbO_2). Noninvasive spectrophotometric measurements of SpO_2 are performed in the visible (600-700nm) and near-infrared (700-1000nm) spectral regions. Pulse oximetry also relies on the detection of photoplethysmographic (PPG) signals produced by variations in the quantity of arterial blood that is associated with periodic contractions and relaxations of the heart. Measurements can be performed in either transmission or reflection modes. In transmission pulse oximetry, the sensor can be attached across a fingertip, foot, or earlobe. In this configuration, the light emitting diodes (LEDs) and photodetector (PD) in the sensor are placed on opposite sides of a peripheral pulsating vascular bed. Alternatively, in reflection pulse oximetry, the LEDs and PD are both mounted side-by-side on the same planar substrate to enable readings from multiple body locations where transillumination measurements are not feasible. Clinically, forehead reflection pulse oximetry has been used as an alternative approach to conventional transmission-based

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*Corresponding author – Y. Mendelson is a Professor in the Department of Biomedical Engineering, Worcester Polytechnic Institute, Worcester, MA 01609 USA (phone: 508-831-5103; fax: 508-831-5541; e-mail: ym@wpi.edu).

R. J. Duckworth is a Professor in the Department of Electrical and Computer Engineering, Worcester Polytechnic Institute, Worcester, MA 01609 USA (rjduck@ece.wpi.edu).

G. Comtois is a M. S. student in the Department of Biomedical Engineering, Worcester Polytechnic Institute, Worcester, MA 01609 USA (comtoisg@wpi.edu).

oximetry when peripheral circulation to the extremities is compromised.

Pulse oximetry was initially intended for in-hospital use on patients undergoing or recovering from surgery. During the past few years, several companies have developed smaller pulse oximeters, some including data transmission via telemetry, to further expand the applications of pulse oximetry. For example, battery-operated pulse oximeters are now attached to patients during emergency transport as they are being moved from a remote location to a hospital, or between hospital wards. Some companies are also offering smaller units with improved electronic filtering of noisy PPG signals.

Several reports described the development of a wireless pulse oximeter that may be suitable for remote physiological monitoring [3]-[4]. Despite the steady progress in miniaturization of pulse oximeters over the years, to date, the most significant limitation is battery longevity and lack of telemetric communication. In this paper, we describe a prototype forehead-based reflectance pulse oximeter suitable for remote triage applications.

II. SYSTEM ARCHITECTURE

The prototype system, depicted in Fig. 1, consists of a body-worn pulse oximeter that receives and processes the PPG signals measured by a small ($\phi = 22\text{mm}$) and lightweight (4.5g) optical reflectance transducer. The system

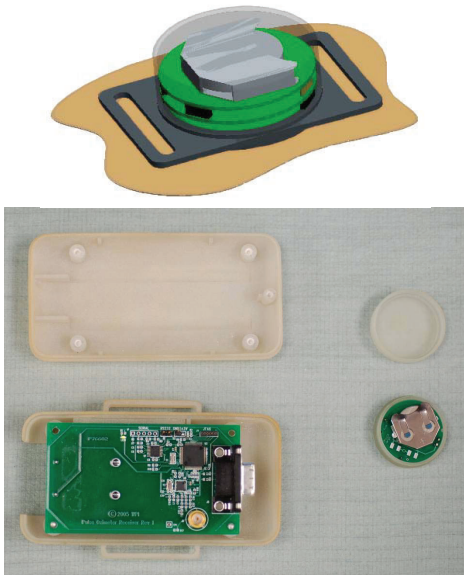


Fig. 1. (Top) Attachment of Sensor Module to the skin; (Bottom) photograph of the Receiver Module (left) and Sensor Module (right).

consists of three units: A Sensor Module, consisting of the optical transducer, a stack of round PCBs, and a coin-cell battery. The information acquired by the Sensor Module is transmitted wirelessly via an RF link over a short range to a body-worn Receiver Module. The data processed by the Receiver Module can be transmitted wirelessly to a PDA. The PDA can monitor multiple wearable pulse oximeters simultaneously and allows medics to collect vital physiological information to enhance their ability to extend more effective care to those with the most urgent needs. The

system can be programmed to alert on alarm conditions, such as sudden trauma, or physiological values out of their normal range. It also has the potential for use in combat casualty care, such as for remote triage, and for use by first responders, such as firefighters.

Key features of this system are small-size, robustness, and low-power consumption, which are essential attributes of wearable physiological devices, especially for military applications. The system block diagram (Fig. 2), is described in more detail below.

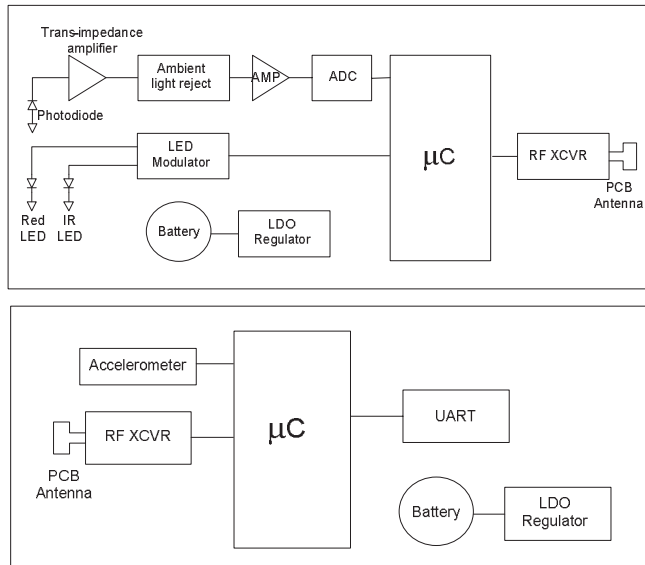


Fig. 2. System block diagram of the wearable, wireless, pulse oximeter. Sensor Module (top), Receiver Module (bottom).

Sensor Module: The Sensor Module contains analog signal processing circuitry, ADC, an embedded microcontroller, and a RF transceiver. The unit is small enough so the entire module can be integrated into a headband or a helmet. The unit is powered by a CR2032 type coin cell battery with 220mAh capacity, providing at least 5 days of operation.

Receiver Module: The Receiver Module contains an embedded microcontroller, RF transceiver for communicating with the Sensor Module, and a Universal Asynchronous Receive Transmit (UART) for connection to a PC. Signals acquired by the Sensor Module are received by the embedded microcontroller which synchronously converts the corresponding PD output to R and IR PPG signals. Dedicated software is used to filter the signals and compute SpO_2 and HR based on the relative amplitude and frequency content of the reflected PPG signals. A tri-axis MEMS accelerometer detects changes in body activity, and the information obtained through the tilt sensing property of the accelerometer is used to determine the orientation of the person wearing the device.

To facilitate bi-directional wireless communications between the Receiver Module and a PDA, we used the DPAC Airborne™ LAN node module (DPAC Technologies, Garden Grove, CA). The DPAC module operates at a frequency of 2.4GHz, is 802.11b wireless compliant, and has a relatively small ($1.6 \times 1.17 \times 0.46$ inches) footprint. The wireless module runs off a 3.7VDC and includes a built-in

(19) **United States**(12) **Patent Application Publication**
Nishikawa et al.(10) **Pub. No.: US 2007/0145255 A1**(43) **Pub. Date: Jun. 28, 2007**(54) **LENS-EQUIPPED LIGHT-EMITTING DIODE
DEVICE AND METHOD OF
MANUFACTURING THE SAME****Publication Classification**(51) **Int. Cl.**
H01J 5/02 (2006.01)**H01J 40/14** (2006.01)(52) **U.S. Cl.** **250/239**(76) Inventors: **Shouichi Nishikawa**, Yokohama-shi
(JP); **Tetsuro Komatsu**, Yokohama-shi
(JP); **Hatsuo Takezawa**, Yokohama-shi
(JP); **Yukinori Aoki**, Yokohama-shi (JP)(57) **ABSTRACT**

Correspondence Address:

**OBLON, SPIVAK, MCCLELLAND, MAIER &
NEUSTADT, P.C.**
1940 DUKE STREET
ALEXANDRIA, VA 22314 (US)

A lens-equipped light-emitting diode device of the present invention includes a lead frame in which an electrode is formed, a light-emitting diode which is mounted on the electrode of the lead frame, an outer peripheral unit which is made of a first resin, which is provided on the lead frame, and in which a hollow portion is formed while an area including at least the light-emitting diode is exposed in the outer peripheral unit, a sealing portion which is made of a second resin filled in the lead frame of the hollow portion of the outer peripheral unit, and which seals the light-emitting diode, and a lens unit made of a third resin laminated and filled in the sealing portion.

(21) Appl. No.: **11/613,503**(22) Filed: **Dec. 20, 2006**(30) **Foreign Application Priority Data**

Dec. 26, 2005 (JP) 2005-373498

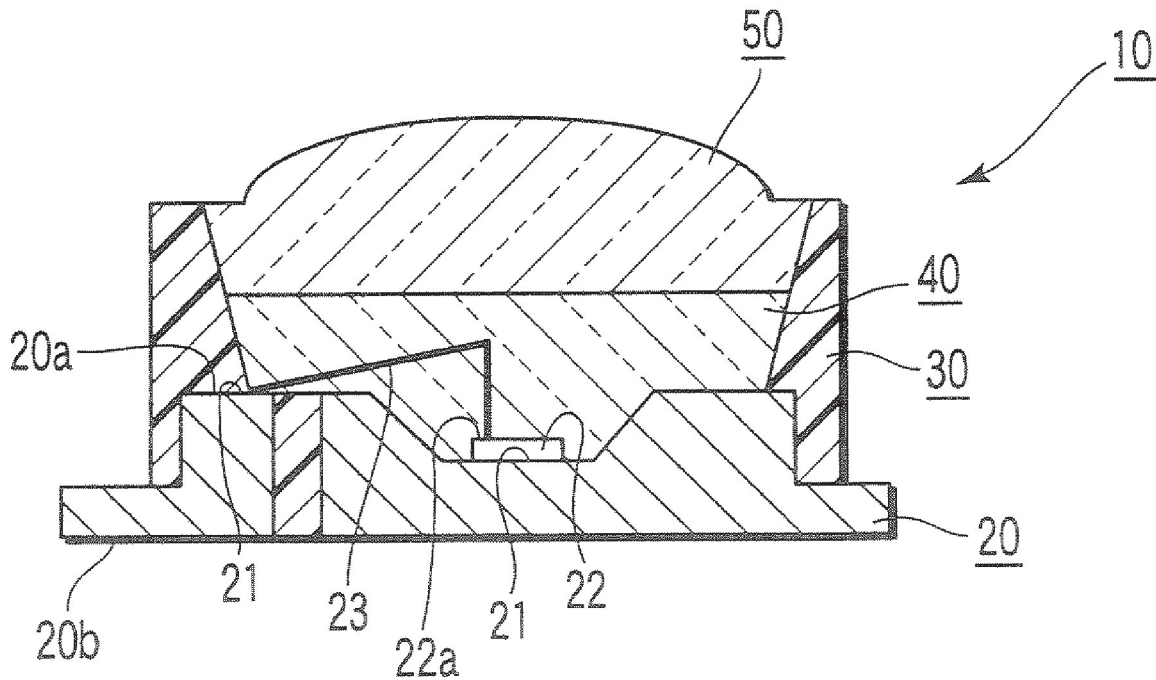


FIG. 1

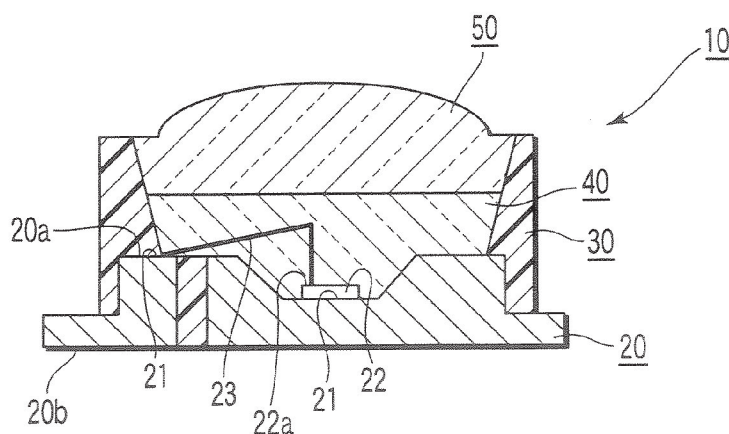


FIG. 2

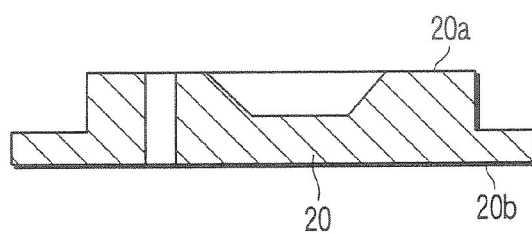


FIG. 3

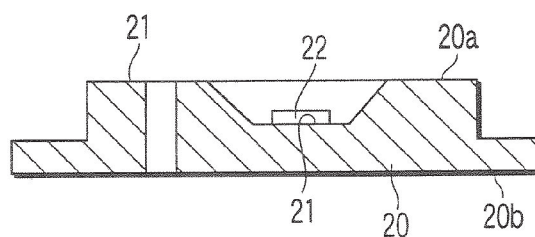


FIG. 4

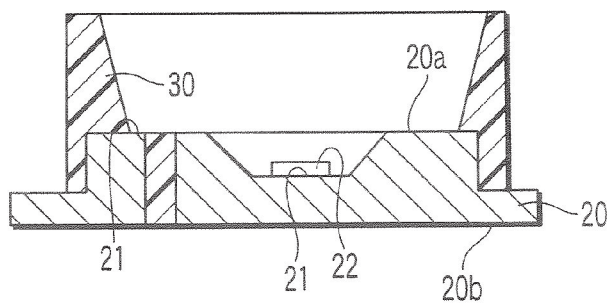


FIG. 5

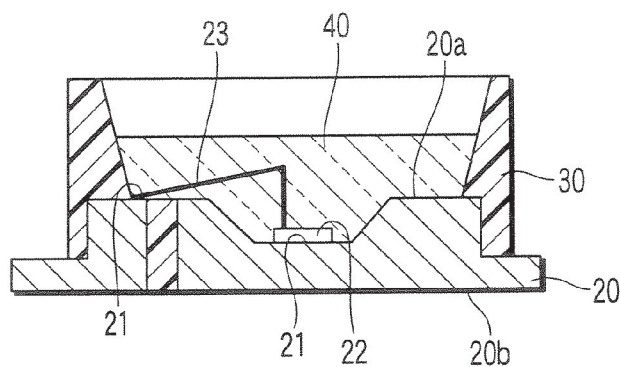


FIG. 6

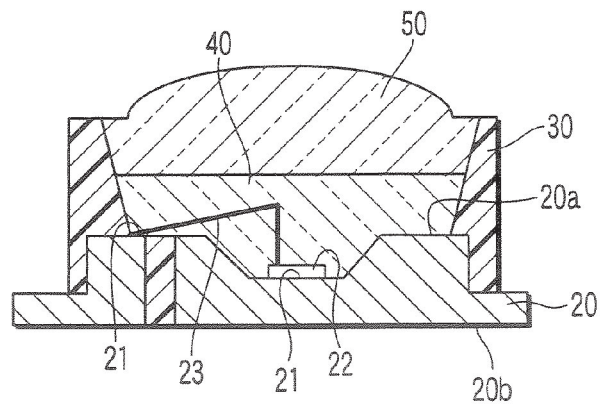


FIG. 7

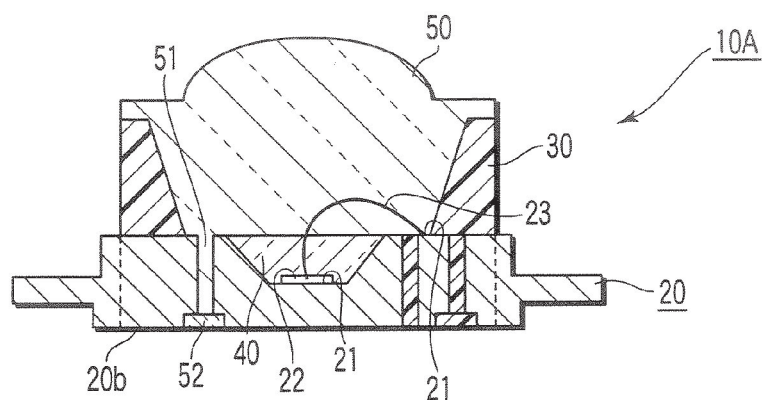


FIG. 8

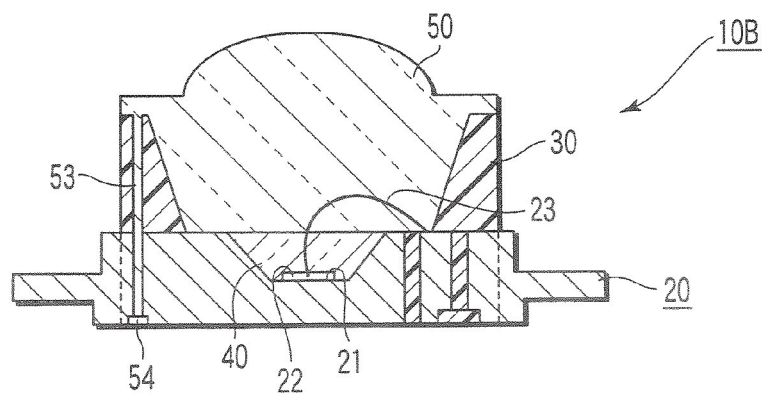


FIG. 9

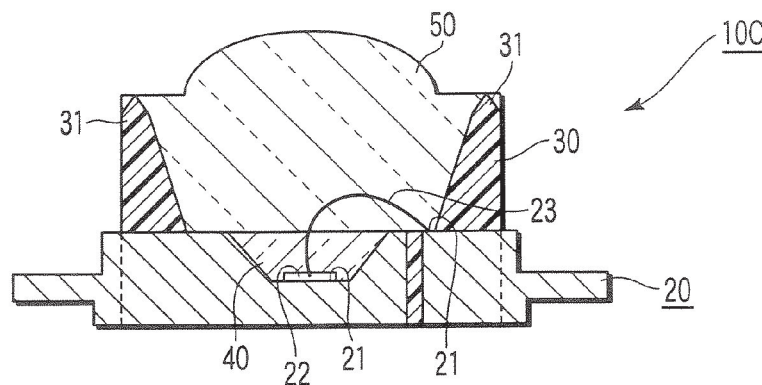


FIG. 10

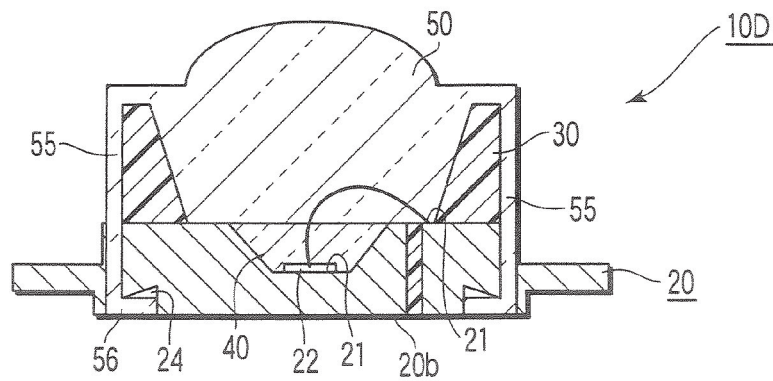


FIG. 11

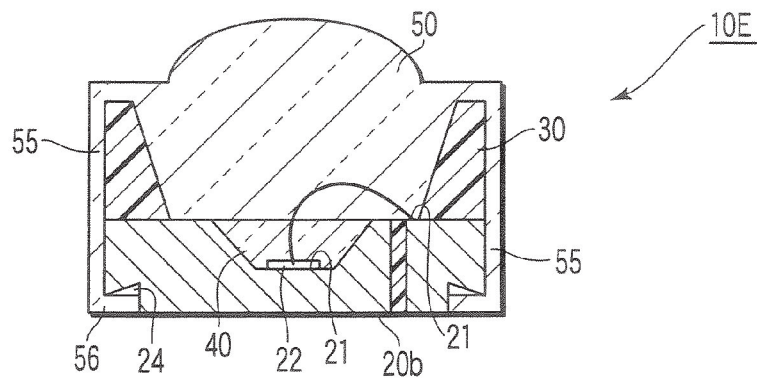


FIG. 12

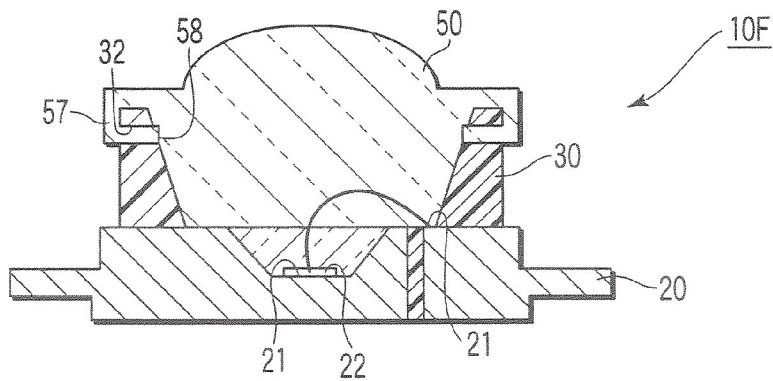
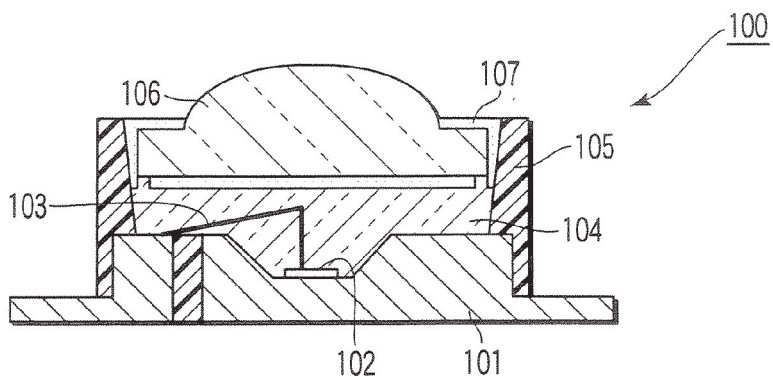


FIG. 13
(PRIOR ART)



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LENS-EQUIPPED LIGHT-EMITTING DIODE DEVICE AND METHOD OF MANUFACTURING THE SAME

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is based upon and claims the benefit of priority from prior Japanese Patent Application No. 2005-373498, filed Dec. 26, 2005, the entire contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates to a lens-equipped light-emitting diode device which extracts light from a light-emitting diode through a lens and a method of manufacturing the same, and particularly to a lens-equipped light-emitting diode device which is excellent for light extraction efficiency and reliability and whose production cost can be reduced.

[0004] 2. Description of the Related Art

[0005] FIG. 13 is a longitudinal sectional view showing a conventional lens-equipped light-emitting diode device 100. In the lens-equipped light-emitting diode device 100, a light-emitting diode element 102 is mounted through a die mounting material (not shown) on a lead frame 101 in which an electrode is formed, and an electrode of the light-emitting diode element 102 and an electrode exposed outside the lead frame are connected by a bonding wire 103.

[0006] A sealing portion 104 made of resin is formed around the light-emitting diode element 102, and an outer peripheral unit 105 is formed outside the lead frame 101 and light-emitting diode element 102 using a white thermoplastic resin. A lens 106 is attached to upwardly collect light emitted from the light-emitting diode element, and the lens 106 is made of a transparent resin produced in a different process. In FIG. 13, the number 107 designates a bonding agent.

[0007] Generally a transparent resin is used as the sealing portion 104. Recently, a white light-emitting diode device is proceeding toward the practical use in illumination. In this case, frequently a fluorescent material for converting blue or UV light emitted from the light-emitting diode element is mixed into the transparent resin.

[0008] In the conventional lens-equipped light-emitting diode device, the lens 106 produced in the different process is attached to the outer peripheral unit 105 by bonding or fitting. A method of casting a thermosetting resin into the outer peripheral unit 105 is also adopted (for example, see Jpn. Pat. Appln. KOKAI Publication No. 2004-343059).

[0009] In the conventional lens-equipped light-emitting diode device, there are the following problems. In the case where the lens 106 is attached to the outer peripheral unit 105 by bonding or fitting, sometimes a micro-gap is generated between the sealing portion 104 and lens 106, which decreases light extraction efficiency. There is also generated the problem that mechanical strength or a heat-resistant property is degraded due to poor adhesion between the lens 106 and the outer peripheral unit 105.

[0010] On the other hand, in a production process, the following factors become an obstacle for reducing assembly cost. That is, an assembly process of attaching the lens 106 to the outer peripheral unit 105 is required, and an optical axis adjustment process is required to accurately attaching the lens 106 to the outer peripheral unit 105. In the case where the lens 106 is formed by casting, only the thermosetting resin is used. However, generally a long-time curing process is required for the casting, so that the cost reduction also becomes the problem in the casting.

BRIEF SUMMARY OF THE INVENTION

[0011] In view of the foregoing, an object of the invention is to provide a lens-equipped light-emitting diode which is excellent in light extraction efficiency and reliability while production cost can be reduced, and a production method thereof.

[0012] In order to achieve the object, the lens-equipped light-emitting diode device according to the invention and the production method thereof have the following configurations.

[0013] A lens-equipped light-emitting diode device comprises: a support member in which an electrode is formed; a light-emitting diode which is mounted on the electrode of the support member; an outer peripheral unit which is provided on the support member, a hollow portion being formed while an area including at least the light-emitting diode is exposed in the outer peripheral unit made of a first resin; a sealing portion which is made of a second resin, the support member side of the hollow portion of the outer peripheral unit being filled with the second resin to seal the light-emitting diode; and a lens unit which is made of a third resin, the lens unit being laminated on the sealing portion by integral molding.

[0014] A method of producing a lens-equipped light-emitting diode device comprises: a process of mounting a light-emitting diode element on a support member; a first positioning process of positioning the support member in a first die; an outer peripheral unit forming process of supplying a resin into the first die to form an outer peripheral unit; a sealing process of sealing the light-emitting diode element; a second positioning process of positioning the support member in a second die; and a lens unit forming process of supplying a resin into the second die to form a lens unit.

[0015] Additional objects and advantages of the invention will be set forth in the description which follows, and in part will be obvious from the description, or may be learned by practice of the invention. The objects and advantages of the invention may be realized and obtained by means of the instrumentalities and combinations particularly pointed out hereinafter.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING

[0016] The accompanying drawings, which are incorporated in and constitute a part of the specification, illustrate embodiments of the invention, and together with the general description given above and detailed description of the embodiments given below, serve to explain the principles of the invention.

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[0017] FIG. 1 is a longitudinal sectional view showing a lens-equipped light-emitting diode device according to a first embodiment of the invention;

[0018] FIG. 2 is a longitudinal sectional view showing a process of producing the lens-equipped light-emitting diode device according to the first embodiment;

[0019] FIG. 3 is a longitudinal sectional view showing a process of producing the lens-equipped light-emitting diode device according to the first embodiment;

[0020] FIG. 4 is a longitudinal sectional view showing a process of producing the lens-equipped light-emitting diode device according to the first embodiment;

[0021] FIG. 5 is a longitudinal sectional view showing a process of producing the lens-equipped light-emitting diode device according to the first embodiment;

[0022] FIG. 6 is a longitudinal sectional view showing a process of producing the lens-equipped light-emitting diode device according to the first embodiment;

[0023] FIG. 7 is a longitudinal sectional view showing a lens-equipped light-emitting diode device according to a second embodiment of the invention;

[0024] FIG. 8 is a longitudinal sectional view showing a lens-equipped light-emitting diode device according to a third embodiment of the invention;

[0025] FIG. 9 is a longitudinal sectional view showing a lens-equipped light-emitting diode device according to a fourth embodiment of the invention;

[0026] FIG. 10 is a longitudinal sectional view showing a lens-equipped light-emitting diode device according to a fifth embodiment of the invention;

[0027] FIG. 11 is a longitudinal sectional view showing a lens-equipped light-emitting diode device according to a sixth embodiment of the invention;

[0028] FIG. 12 is a longitudinal sectional view showing a lens-equipped light-emitting diode device according to a seventh embodiment of the invention; and

[0029] FIG. 13 is a longitudinal sectional view showing an example of a conventional lens-equipped light-emitting diode device.

DETAILED DESCRIPTION OF THE INVENTION

[0030] FIG. 1 is a longitudinal sectional view showing a lens-equipped light-emitting diode device 10 according to a first embodiment of the invention. The lens-equipped light-emitting diode device 10 includes a lead frame 20, an outer peripheral unit 30, a sealing portion 40, and a lens unit 50. The lead frame 20 is a support member in which an electrode is formed. The outer peripheral unit 30 is formed on the lead frame 20. The sealing portion 40 is provided in the outer peripheral unit 30 and seals a light-emitting diode 22 and a bonding wire 23. The lens unit 50 is arranged in an upper portion of the sealing portion 40.

[0031] Plural electrodes 21 are formed on the side of a surface 20a of the lead frame 20, and a light-emitting diode 22 is mounted on the electrode 21. A bonding wire 23 is connected to one of the electrodes of the light-emitting diode

22, and the bonding wire 23 is connected to the electrode 21. In FIG. 1, the number 20b designates a backside of the lead frame 20.

[0032] A white color thermoplastic resin such as PPA, PC, and epoxy resin is used as a first resin forming the outer peripheral unit 30. A thermosetting resin or a UV curing resin, such as a transparent epoxy resin and transparent silicone, is used as a second resin forming the sealing portion 40. In the case of the device which emits white light, sometimes a fluorescent material for wavelength conversion is mixed to the resin. The thermosetting resin such as the transparent epoxy resin and the transparent silicone or the thermoplastic resin such as PMMA, PC, and COP is used as a third resin forming the lens unit 50.

[0033] A method of producing the lens-equipped light-emitting diode device 10 will be described below. The lead frame 20 is prepared as shown in FIG. 2, and the light-emitting diode element is mounted on the lead frame with a die mounting material (not shown) as shown in FIG. 3. Then, these components are inserted in an injection molding die to form the outer peripheral unit 30 using a first white thermoplastic resin as shown in FIG. 4.

[0034] As shown in FIG. 5, wire bonding is performed between the electrode of the light-emitting diode element 22 and the electrode 21 of the lead frame 20, and the sealing portion 40 is formed around the light-emitting diode element 22 using a second sealing resin. At this point, the sealing portion 40 may be formed by the injection mold with the die or a potting method.

[0035] These molded components are inserted in the injection molding die different from those for molding the outer peripheral unit 30 and the sealing portion 40, and a lens unit 50 is integrally molded using a third transparent resin as shown in FIG. 6. A LIM method is adopted in the case where the thermosetting resin is used, and the injection molding method is adopted in the case where the thermoplastic resin is used.

[0036] In the lens-equipped light-emitting diode device 10 formed in the above-described manner, because the molding of the lens unit 50 and the attachment of the lens unit 50 to the outer peripheral unit 30 can simultaneously be performed, a process of attaching a resin lens produced by another process to the outer peripheral unit and a process of adjusting an optical axis are not required, which allows cost to be reduced in an assembly process.

[0037] A gap generated between the lens unit 50 and the outer peripheral unit 30 and a gap generated between the lens unit 50 and the sealing portion 40 can be prevented to improve the light extraction efficiency. Furthermore, attachment strength can be enhanced because the resins are fused at a boundary surface between the lens unit 50 and the sealing portion 40.

[0038] Thus, the lens-equipped light-emitting diode device of the first embodiment is excellent in the light extraction efficiency and the reliability, and the production cost can be reduced.

[0039] FIG. 7 is a longitudinal sectional view showing a lens-equipped light-emitting diode device 10A according to a second embodiment of the invention. In FIG. 7, the same

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components as those of FIG. 1 are designated by the same numbers, and detailed description thereof will be omitted.

[0040] A penetration portion 51 is provided in the lens unit 50, and the penetration portion 51 is latched in the lead frame 20 at a front-edge portion 52 of the penetration portion 51. The penetration portion 51 penetrates the lead frame 20 to the backside 20b where the light-emitting diode 22 is not mounted.

[0041] In the lens-equipped light-emitting diode device 10A of the second embodiment, the same effect as the lens-equipped light-emitting diode device 10 can also be obtained. The lens-equipped light-emitting diode device 10A further has the following effect. In the case where the resins forming the outer peripheral unit 30 and the lens unit 50 are different from each other, it is difficult to secure adhesive strength between the outer peripheral unit 30 and the lens unit 50. Therefore, in the integral molding with the lens unit 50, the penetration portion 51 is formed to prevent drop-out of the lens unit 50 in such a manner that the penetration portion 51 is filled with a transparent resin to the backside 20b of the lead frame 20. This enables the adhesive strength to be enhanced to improve the reliability. The resin having a large shrinkage ratio and linear thermal expansion coefficient is used as the third resin forming the lens unit 51, which allows the effect to be increased. The thermoplastic resin or the thermosetting resin can be used as the third resin.

[0042] FIG. 8 is a longitudinal sectional view showing a lens-equipped light-emitting diode device 10B according to a third embodiment of the invention. In FIG. 8, the same components as those of FIG. 1 are designated by the same numbers, and detailed description thereof will be omitted.

[0043] A penetration portion 53 is provided in the lens unit 50, and the penetration portion 53 is latched in the lead frame 20 at a front-edge portion 54 of the penetration portion 53. The penetration portion 53 penetrates the outer peripheral unit 30 and the lead frame 20 to the backside 20b where the light-emitting diode 22 is not mounted.

[0044] In the lens-equipped light-emitting diode device 10B of the third embodiment, the same effect as the lens-equipped light-emitting diode device 10A can also be obtained.

[0045] FIG. 9 is a longitudinal sectional view showing a lens-equipped light-emitting diode device 10C according to a fourth embodiment of the invention. In FIG. 9, the same components as those of FIG. 1 are designated by the same numbers, and detailed description thereof will be omitted.

[0046] In the fourth embodiment, a micro-rib 31 is provided in an upper edge portion of the outer peripheral unit 30. In the lens-equipped light-emitting diode device 10C of the fourth embodiment, the same effect as the lens-equipped light-emitting diode device 10 can also be obtained, and only the micro-rib 31 is re-melted to weld the lens unit 50 by heat of the transparent resin when the lens unit 50 is molded. At this point, the welding strength can be enhanced by utilizing the resin having a higher melting point. In this case, the thermoplastic resin is used as the first resin and the third resin.

[0047] FIG. 10 is a longitudinal sectional view showing a lens-equipped light-emitting diode device 10D according to a fifth embodiment of the invention. In FIG. 10, the same components as those of FIG. 1 are designated by the same numbers, and detailed description thereof will be omitted.

[0048] A notch portion 24 is provided in the lead frame 20. A latch portion 55 is provided in the lens unit 50, and a front-edge portion 56 of the latch portion 55 is engaged with the notch portion 24. The latch portion 55 penetrates the lead frame 20, and is extended to the backside 20b where the light-emitting diode 22 is not mounted.

[0049] In the lens-equipped light-emitting diode device 10D of the fifth embodiment, the same effect as the lens-equipped light-emitting diode device 10A can also be obtained.

[0050] FIG. 11 is a longitudinal sectional view showing a lens-equipped light-emitting diode device 10E according to a sixth embodiment of the invention. In FIG. 11, the same components as those of FIG. 1 are designated by the same numbers, and detailed description thereof will be omitted.

[0051] The lens-equipped light-emitting diode device 11E can be applied to the case where the latch portion 55 is provided in a side face different from that of the lens-equipped light-emitting diode device 10D. The notch portion 24 is provided in the lead frame 20. The latch portion 55 is also provided in the lens unit 50, and the front-edge portion 56 of the latch portion 55 is engaged with the notch portion 24. The latch portion 55 is extended along the side face of the lead frame 20, and the latch portion 55 is extended to the backside 20b where the light-emitting diode 22 is not mounted.

[0052] In the lens-equipped light-emitting diode device 10E of the sixth embodiment, the same effect as the lens-equipped light-emitting diode device 10D can also be obtained. In the lens-equipped light-emitting diode device 10E, it is not necessary that the latch portion 55 penetrate the lead frame 20.

[0053] FIG. 12 is a longitudinal sectional view showing a lens-equipped light-emitting diode device 10F according to a seventh embodiment of the invention. In FIG. 12, the same components as those of FIG. 1 are designated by the same numbers, and detailed description thereof will be omitted.

[0054] A through hole 32 is provided in the outer peripheral unit 30. A latch portion 57 is provided in the lens unit 50 while inserted into the through hole 32, and a front-edge portion 58 is engaged with the through hole 32. The notch portion may be provided in place of the through hole 32.

[0055] In the lens-equipped light-emitting diode device 10F of the seventh embodiment, the same effect as the lens-equipped light-emitting diode device 10A can also be obtained.

[0056] The structures and processes in the above embodiments are illustrated by way of example, and obviously the structures and processes may be replaced as appropriate. For example, the electrode of the light-emitting diode element 22 may be connected to the external electrode 21 not by the wire bonding but by the flip chip bonding. In the production process, the light-emitting diode element 22 may be mounted after the outer peripheral unit 30 is formed in the lead frame 20 using the white resin. The lens integral molding can also be injection-molded not on the lead frame 20 but on a support member in which the electrode is formed, e.g., a glass epoxy substrate and a ceramic substrate.

[0057] The invention is not limited to the above embodiments, but various modifications could be made without departing from the scope of the invention. Various inventions could also be made by the appropriate combination of the plural components disclosed in the embodiments. For

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example, some components shown in the embodiments can be eliminated from all the components. The components in the different embodiments may appropriately be combined.

[0058] Additional advantages and modifications will readily occur to those skilled in the art. Therefore, the invention in its broader aspects is not limited to the specific details and representative embodiments shown and described herein. Accordingly, various modifications may be made without departing from the spirit or scope of the general inventive concept as defined by the appended claims and their equivalents.

What is claimed is:

1. A lens-equipped light-emitting diode device comprising:

- a support member in which an electrode is formed;
- a light-emitting diode which is mounted on the electrode of the support member;
- an outer peripheral unit which is provided on the support member, a hollow portion being formed while an area including at least the light-emitting diode is exposed in the outer peripheral unit made of a first resin;
- a sealing portion which is made of a second resin, the support member side of the hollow portion of the outer peripheral unit being filled with the second resin to seal the light-emitting diode; and
- a lens unit which is made of a third resin, the lens unit being laminated on the sealing portion by integral molding.

2. The lens-equipped light-emitting diode device according to claim 1, wherein the first resin is a white resin.

3. The lens-equipped light-emitting diode device according to claim 1, wherein the second resin is a transparent thermosetting resin, a transparent UV curing resin, or a material in which a fluorescent material for wavelength conversion is mixed with each of the transparent resins.

4. The lens-equipped light-emitting diode device according to claim 1, wherein the third resin is a transparent thermosetting resin or a transparent thermoplastic resin.

5. The lens-equipped light-emitting diode device according to claim 1, wherein the lens unit has an engagement portion which is engaged with the support member or the outer peripheral unit.

6. The lens-equipped light-emitting diode device according to claim 5 wherein the engagement portion has a penetration portion which is pierced to a backside from a surface on which the light-emitting diode element is mounted.

7. The lens-equipped light-emitting diode device according to claim 5, wherein the engagement portion has a penetration portion which is pierced from the outer peripheral unit to a backside of a surface of the support member on which the light-emitting diode element is mounted.

8. The lens-equipped light-emitting diode device according to claim 5, wherein the first resin and the third resin are a thermoplastic resin, and

the engagement portion has a micro projection and a fusion portion, the micro projection being formed in an upper edge portion of the outer peripheral unit, the fusion portion being generated by melting the micro projection and the lens unit.

9. The lens-equipped light-emitting diode device according to claim 5, wherein the engagement portion has a latch member which is latched in a backside of a surface of the support member on which the light-emitting diode element is mounted.

10. A method of producing a lens-equipped light-emitting diode device comprising:

mounting a light-emitting diode element on a support member;

first positioning the support member in a first die;

supplying a resin into the first die to form an outer peripheral unit;

sealing the light-emitting diode element;

second positioning the support member in a second die; and

supplying a resin into the second die to form a lens unit.

11. The method of producing a lens-equipped light-emitting diode device according to claim 10, wherein the resin supplied into the first die is a white resin.

12. The method of producing a lens-equipped light-emitting diode device according to claim 10, wherein a resin seals the light-emitting diode, and

the resin is a transparent thermosetting resin, a transparent UV curing resin, or a material in which a fluorescent material for wavelength conversion is mixed with each of the transparent resins.

13. The method of producing a lens-equipped light-emitting diode device according to claim 10, wherein the resin supplied into the second die is a transparent thermosetting resin or a transparent thermoplastic resin.

14. The method of producing a lens-equipped light-emitting diode device according to claim 10, wherein the lens unit is an engagement portion which is engaged with the support member or the outer peripheral unit.

15. The method of producing a lens-equipped light-emitting diode device according to claim 14, wherein the engagement portion has a penetration portion which is pierced to a backside from a surface on which the light-emitting diode element is mounted.

16. The method of producing a lens-equipped light-emitting diode device according to claim 14, wherein the engagement portion has a penetration portion which is pierced from the outer peripheral unit to a backside of a surface of the support member on which the light-emitting diode element is mounted.

17. The method of producing a lens-equipped light-emitting diode device according to claim 14, wherein the first resin and the third resin are a thermoplastic resin, and

the engagement portion has a micro projection and a fusion portion, the micro projection being formed in an upper edge portion of the outer peripheral unit, the fusion portion being generated by melting the micro projection and the lens unit.

18. The method of producing a lens-equipped light-emitting diode device according to claim 14, wherein the engagement portion has a latch member which is latched in a backside of a surface of the support member on which the light-emitting diode element is mounted.

* * * * *



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(12) **United States Patent**
Mendelson

(10) **Patent No.:** **US 6,801,799 B2**
(45) **Date of Patent:** **Oct. 5, 2004**

(54) **PULSE OXIMETER AND METHOD OF OPERATION**

(75) Inventor: **Yitzhak Mendelson**, Worcester, MA (US)

(73) Assignee: **Cybro Medical, Ltd.**, Haifa (IL)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **10/360,666**

(22) Filed: **Feb. 6, 2003**

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Related U.S. Application Data

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(30) **Foreign Application Priority Data**

Oct. 5, 2000 (IL) 138884

(51) **Int. Cl.⁷** **A61B 5/00**

(52) **U.S. Cl.** **600/330; 600/322; 600/336**

(58) **Field of Search** 600/310, 322, 600/323, 330, 336

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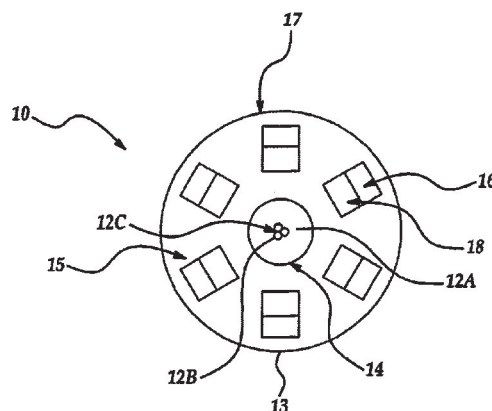
Primary Examiner—Eric F. Winakur

(74) *Attorney, Agent, or Firm*—Howard & Howard

(57) **ABSTRACT**

A sensor for use in an optical measurement device and a method for non-invasive measurement of a blood parameter. The sensor includes sensor housing, a source of radiation coupled to the housing, and a detector assembly coupled to the housing. The source of radiation is adapted to emit radiation at predetermined frequencies. The detector assembly is adapted to detect reflected radiation at least one predetermined frequency and to generate respective signals. The signals are used to determine the parameter of the blood.

5 Claims, 6 Drawing Sheets



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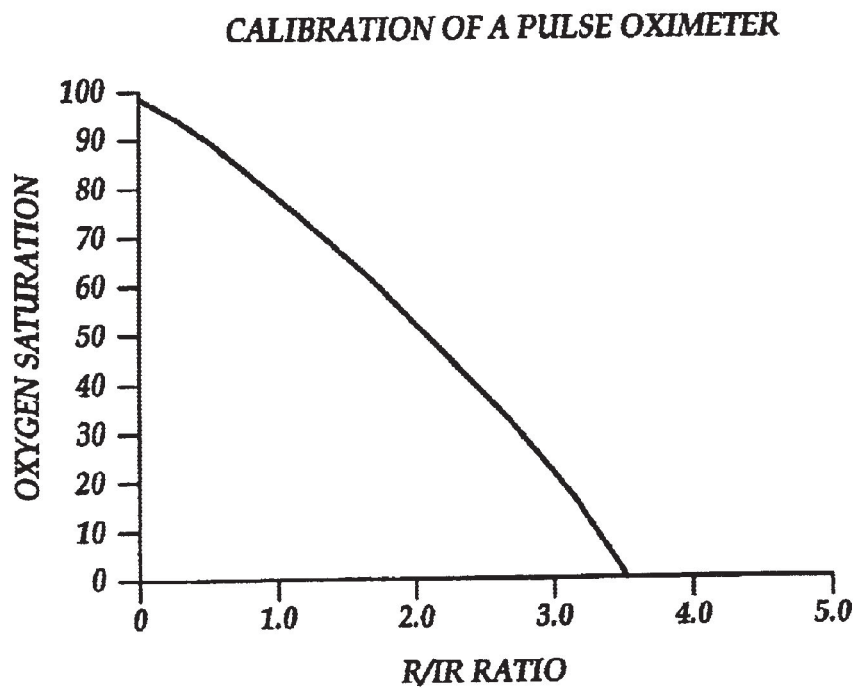
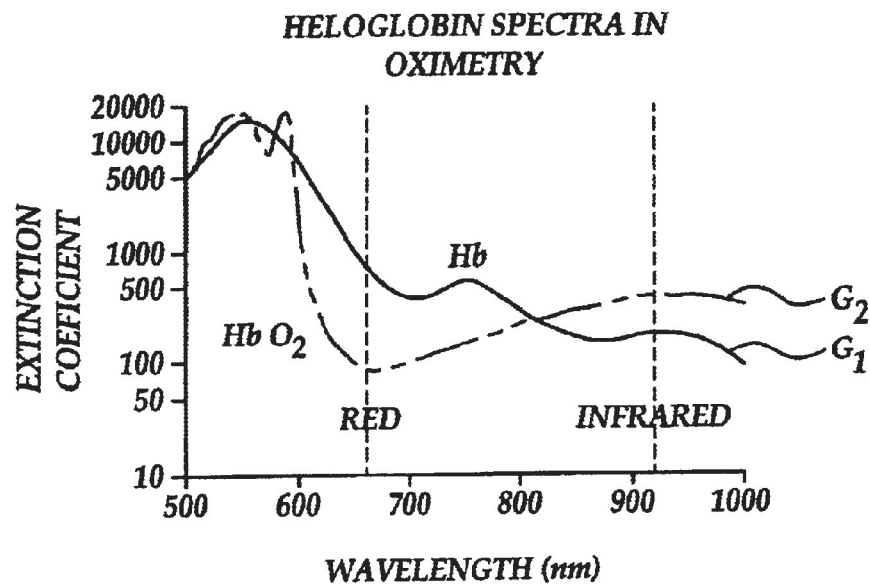
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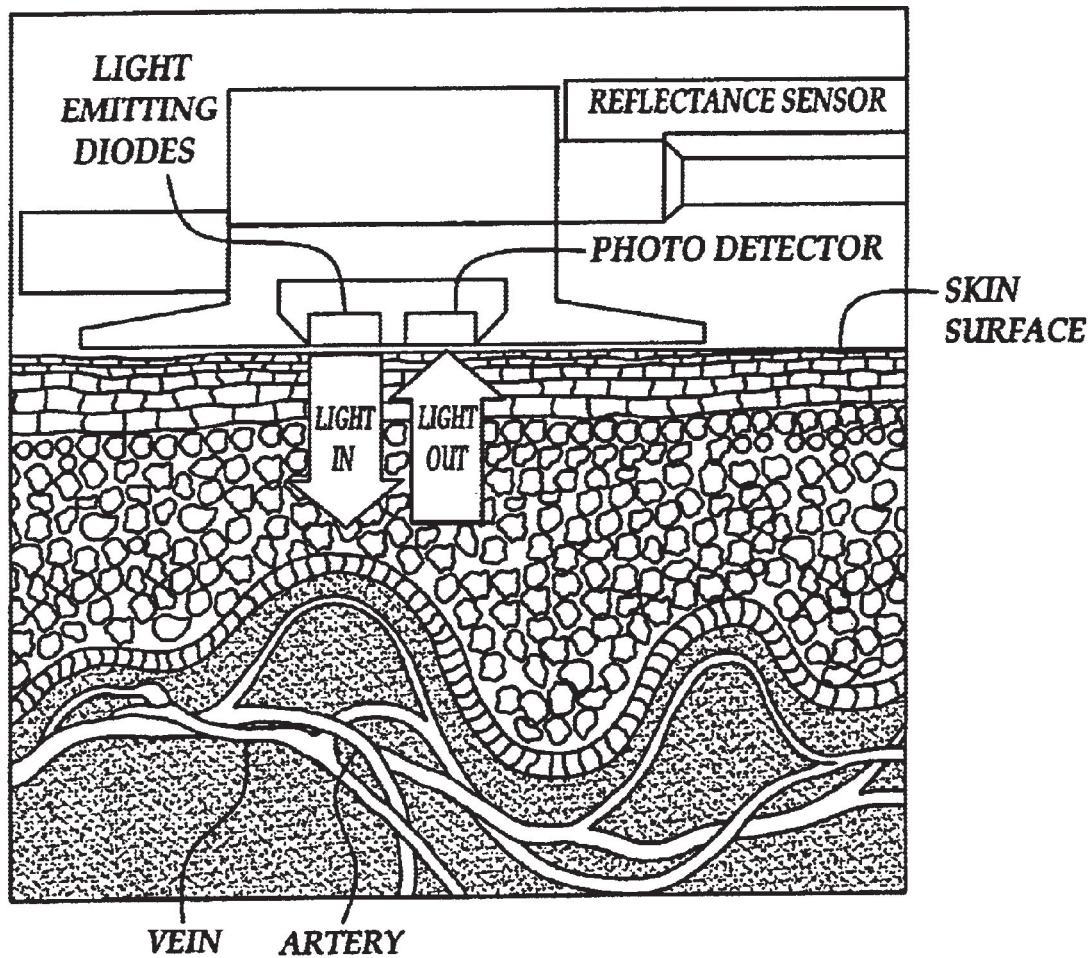


Figure 3

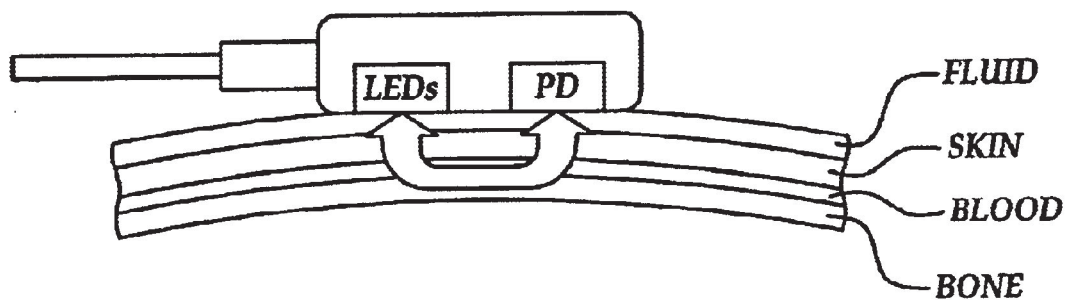


Figure 4

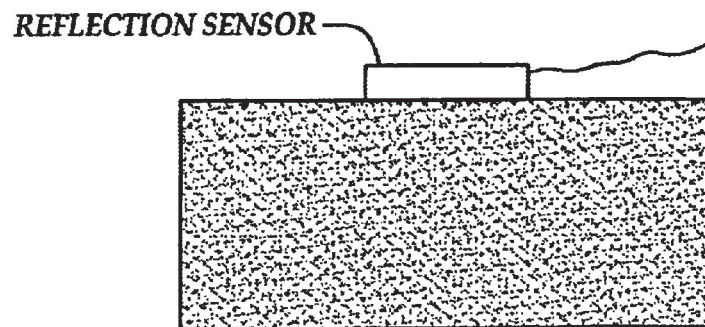


Figure 5A

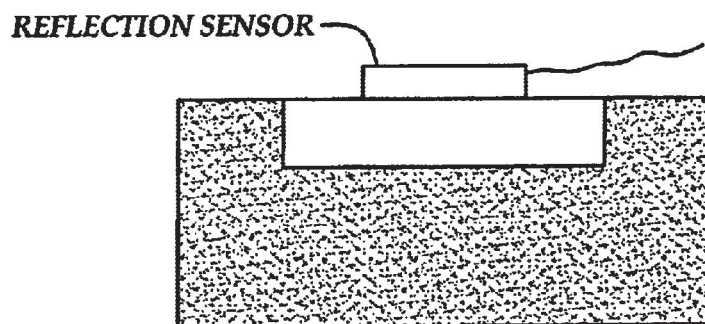


Figure 5B

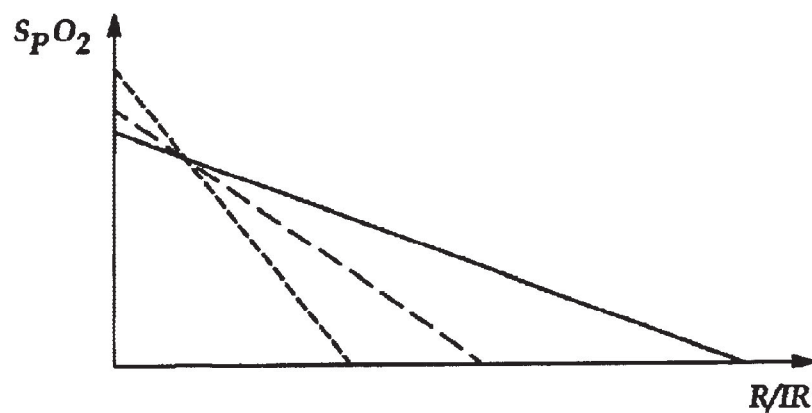


Figure 6

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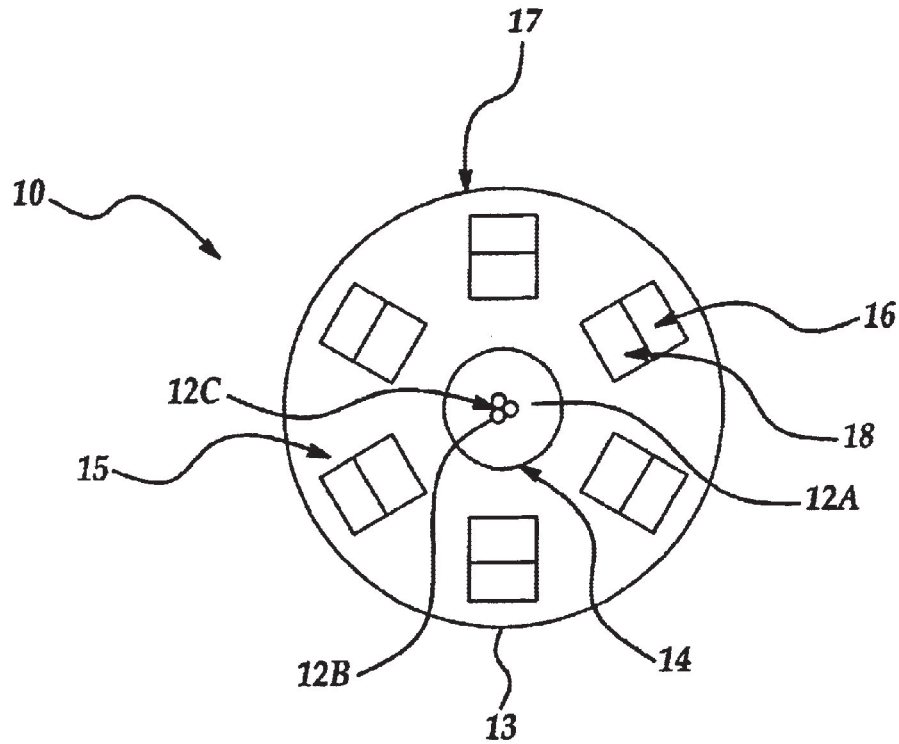


Figure 7

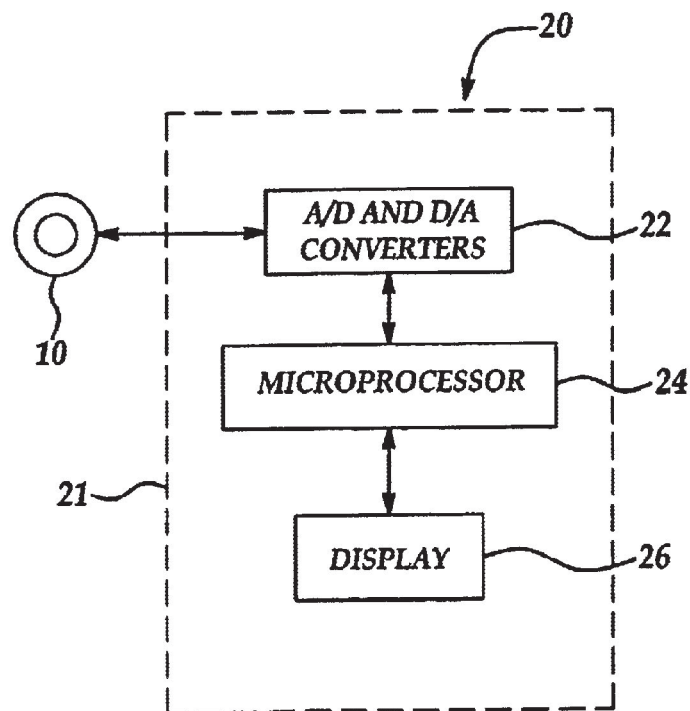


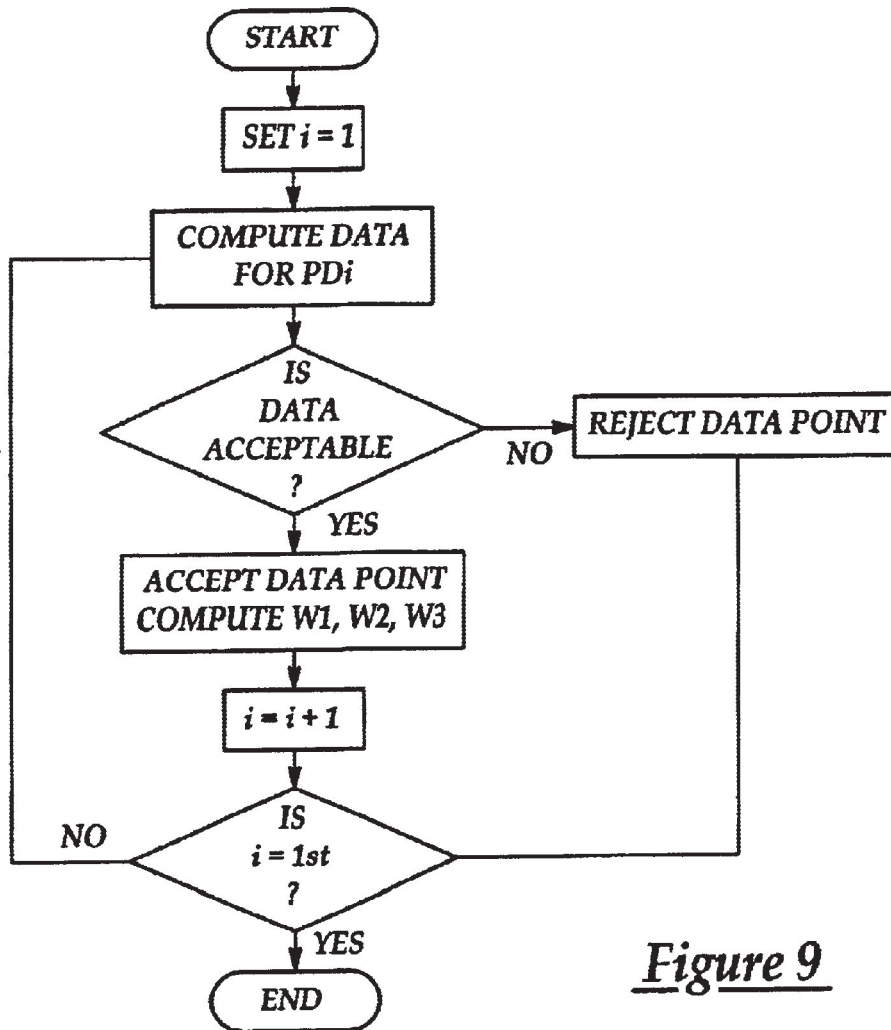
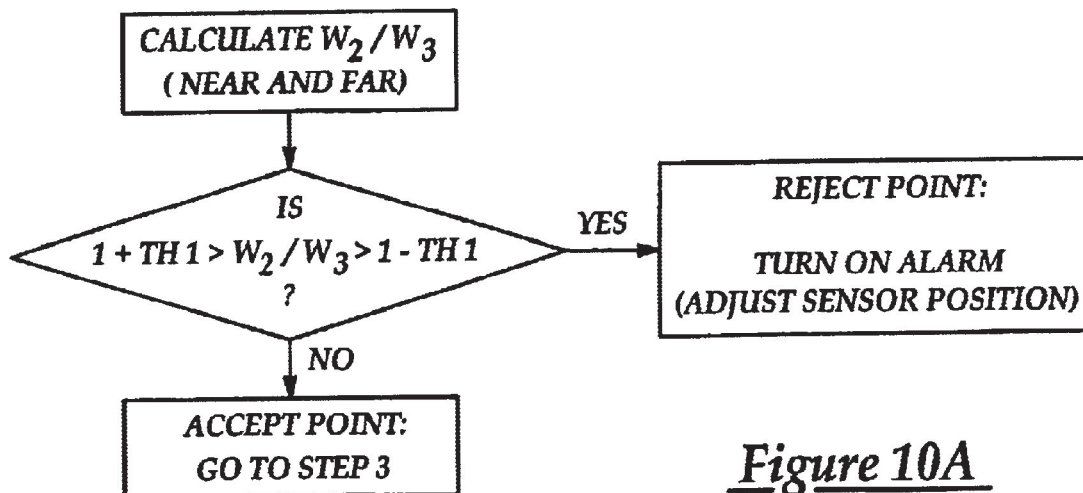
Figure 8

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Figure 9Figure 10A

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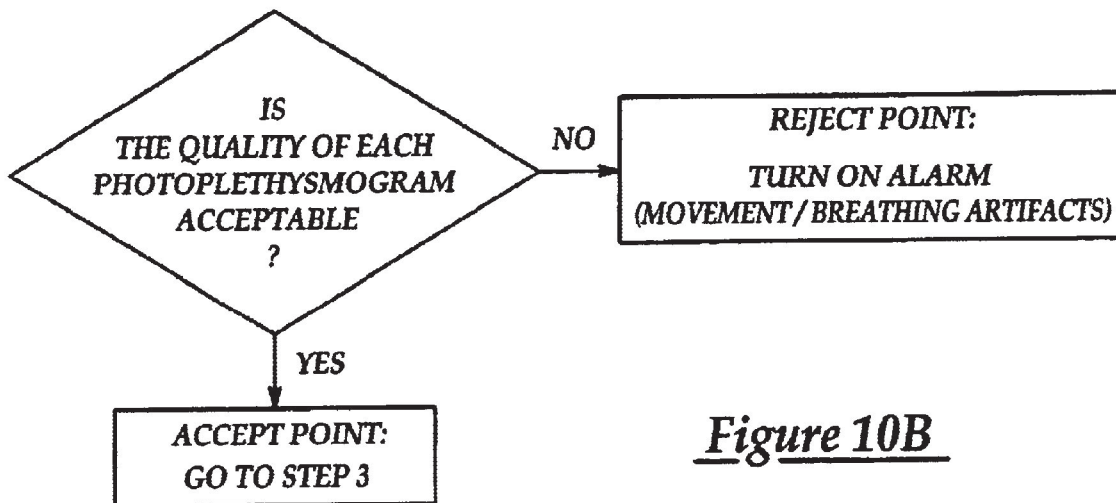


Figure 10B

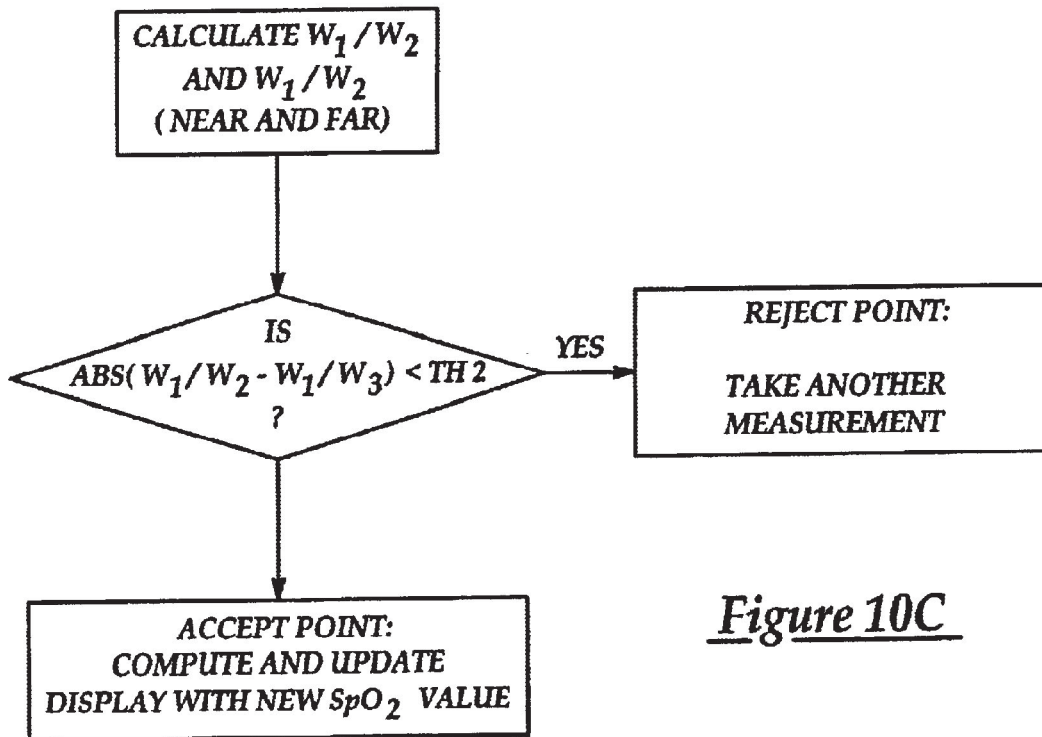


Figure 10C

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PULSE OXIMETER AND METHOD OF OPERATION

This application is a divisional application of U.S. patent application Ser. No. 09/939,391 filed Aug. 24, 2001, now abandoned.

BACKGROUND OF THE INVENTION**1. Field of the Invention**

This invention is generally in the field of pulse oximetry, and relates to a sensor for use in a pulse oximeter, and a method for the pulse oximeter operation.

2. Background of the Invention

Oximetry is based on spectrophotometric measurements of changes in the color of blood, enabling the non-invasive determination of oxygen saturation in the patient's blood. Generally, oximetry is based on the fact that the optical property of blood in the visible (between 500 and 700 nm) and near-infrared (between 700 and 1000 nm) spectra depends strongly on the amount of oxygen in blood.

Referring to FIG. 1, there is illustrated a hemoglobin spectra measured by oximetry based techniques. Graphs G1 and G2 correspond, respectively, to reduced hemoglobin, or deoxyhemoglobin (Hb), and oxygenated hemoglobin, or oxyhemoglobin (HbO₂), spectra. As shown, deoxyhemoglobin (Hb) has a higher optical extinction (i.e., absorbs more light) in the red region of spectrum around 660 nm, as compared to that of oxyhemoglobin (HbO₂). On the other hand, in the near-infrared region of the spectrum around 940 nm, the optical absorption by deoxyhemoglobin (Hb) is lower than the optical absorption of oxyhemoglobin (HbO₂).

Prior art non-invasive optical sensors for measuring arterial oxyhemoglobin saturation (SaO₂) by a pulse oximeter (termed SpO₂) are typically comprised of a pair of small and inexpensive light emitting diodes (LEDs), and a single highly sensitive silicon photodetector. A red (R) LED centered on a peak emission wavelength around 660 nm and an infrared (IR) LED centered on a peak emission wavelength around 940 nm are used as light sources.

Pulse oximetry relies on the detection of a photoplethysmographic signal caused by variations in the quantity of arterial blood associated with periodic contraction and relaxation of a patient's heart. The magnitude of this signal depends on the amount of blood ejected from the heart into the peripheral vascular bed with each systolic cycle, the optical absorption of the blood, absorption by skin and tissue components, and the specific wavelengths that are used to illuminate the tissue. SaO₂ is determined by computing the relative magnitudes of the R and IR photoplethysmograms. Electronic circuits inside the pulse oximeter separate the R and IR photoplethysmograms into their respective pulsatile (AC) and non-pulsatile (DC) signal components. An algorithm inside the pulse oximeter performs a mathematical normalization by which the time-varying AC signal at each wavelength is divided by the corresponding time-invariant DC component which results mainly from the light absorbed and scattered by the bloodless tissue, residual arterial blood when the heart is in diastole, venous blood and skin pigmentation.

Since it is assumed that the AC portion results only from the arterial blood component, this scaling process provides a normalized R/IR ratio (i.e., the ratio of AC/DC values corresponding to R- and IR-spectrum wavelengths, respectively), which is highly dependent on SaO₂, but is largely independent of the volume of arterial blood entering

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the tissue during systole, skin pigmentation, skin thickness and vascular structure. Hence, the instrument does not need to be re-calibrated for measurements on different patients. Typical calibration of a pulse oximeter is illustrated in FIG. 2 by presenting the empirical relationship between SaO₂ and the normalized R/IR ratio, which is programmed by the pulse oximeters' manufacturers.

Pulse oximeters are of two kinds operating, respectively, in transmission and reflection modes. In transmission-mode pulse oximetry, an optical sensor for measuring SaO₂ is usually attached across a fingertip, foot or earlobe, such that the tissue is sandwiched between the light source and the photodetector.

In reflection-mode or backscatter type pulse oximetry, as shown in FIG. 3, the LEDs and photodetector are both mounted side-by-side next to each other on the same planar substrate. This arrangement allows for measuring SaO₂ from multiple convenient locations on the body (e.g. the head, torso, or upper limbs), where conventional transmission-mode measurements are not feasible. For this reason, non-invasive reflectance pulse oximetry has recently become an important new clinical technique with potential benefits in fetal and neonatal monitoring. Using reflectance oximetry to monitor SaO₂ in the fetus during labor, where the only accessible location is the fetal scalp or cheeks, or on the chest in infants with low peripheral perfusion, provides several more convenient locations for sensor attachment.

Reflection pulse oximetry, while being based on similar spectrophotometric principles as the transmission one, is more challenging to perform and has unique problems that can not always be solved by solutions suitable for solving the problems associated with the transmission-mode pulse oximetry. Generally, comparing transmission and reflection pulse oximetry, the problems associated with reflection pulse oximetry consist of the following:

In reflection pulse oximetry, the pulsatile AC signals are generally very small and, depending on sensor configuration and placement, have larger DC components as compared to those of transmission pulse oximetry. As illustrated in FIG. 4, in addition to the optical absorption and reflection due to blood, the DC signal of the R and IR photoplethysmograms in reflection pulse oximetry can be adversely affected by strong reflections from a bone. This problem becomes more apparent when applying measurements at such body locations as the forehead and the scalp, or when the sensor is mounted on the chest over the ribcage. Similarly, variations in contact pressure between the sensor and the skin can cause larger errors in reflection pulse oximetry (as compared to transmission pulse oximetry) since some of the blood near the superficial layers of the skin may be normally displaced away from the sensor housing towards deeper subcutaneous structures. Consequently, the highly reflective bloodless tissue compartment near the surface of the skin can cause large errors even at body locations where the bone is located too far away to influence the incident light generated by the sensor.

Another problem with currently available reflectance sensors is the potential for specular reflection caused by the superficial layers of the skin, when an air gap exists between the sensor and the skin, or by direct shunting of light between the LEDs and the photodetector through a thin layer of fluid which may be due to excessive sweating or from amniotic fluid present during delivery.

It is important to keep in mind the two fundamental assumptions underlying the conventional dual-wavelength pulse oximetry, which are as follows:

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(1) the path of light rays with different illuminating wavelengths in tissue are substantially equal and, therefore, cancel each other; and (2) each light source illuminates the same pulsatile change in arterial blood volume.

Furthermore, the correlation between optical measurements and tissue absorptions in pulse oximetry are based on the fundamental assumption that light propagation is determined primarily by absorbable due to Lambert-Beer's law neglecting multiple scattering effects in biological tissues. In practice, however, the optical paths of different wavelengths in biological tissues is known to vary more in reflectance oximetry compared to transmission oximetry, since it strongly depends on the light scattering properties of the illuminated tissue and sensor mounting.

Several human validation studies, backed by animal investigations, have suggested that uncontrollable physiological and physical parameters can cause large variations in the calibration curve of reflectance pulse oximeters primarily at low oxygen saturation values below 70%. It was observed that the accuracy of pulse oximeters in clinical use might be adversely affected by a number of physiological parameters when measurements are made from sensors attached to the forehead, chest, or the buttock area. While the exact sources of these variations are not fully understood, it is generally believed that there are a few physiological and anatomical factors that may be the major source of these errors. It is also well known for example that changes in the ratio of blood to bloodless tissue volumes may occur through venous congestion, vasoconstriction/vasodilatation, or through mechanical pressure exerted by the sensor on the skin.

Additionally, the empirically derived calibration curve of a pulse oximeter can be altered by the effects of contact pressure exerted by the probe on the skin. This is associated with the following. The light paths in reflectance oximetry are not well defined (as compared to transmission oximetry), and thus may differ between the red and infrared wavelengths. Furthermore, the forehead and scalp areas consist of a relatively thin subcutaneous layer with the cranium bone underneath, while the tissue of other anatomical structures, such as the buttock and limbs, consists of a much thicker layer of skin and subcutaneous tissues without a nearby bony support that acts as a strong light reflector.

Several in vivo and in vitro studies have confirmed that uncontrollable physiological and physical parameters (e.g., different amounts of contact pressure applied by the sensor on the skin, variation in the ratio of bloodless tissue-to-blood content, or site-to-site variations) can often cause large errors in the oxygen saturation readings of a pulse oximeter, which are normally derived based on a single internally-programmed calibration curve. The relevant in vivo studies are disclosed in the following publications:

1. Dassel, et al., "Effect of location of the sensor on reflectance pulse oximetry", *British Journal of Obstetrics and Gynecology*, vol. 104, pp. 910-916, (1997);

2. Dassel, et al., "Reflectance pulse oximetry at the forehead of newborns: The influence of varying pressure on the probe", *Journal of Clinical Monitoring*, vol. 12, pp. 421-428, (1996).

The relevant in vitro studies are disclosed, for example in the following publication:

3. Edrich et al., "Fetal pulse oximetry: influence of tissue blood content and hemoglobin concentration in a new in-vitro model", *European Journal of Obstetrics and Gynecology and Reproductive Biology*, vol. 72, suppl. 1, pp. S29-S34, (1997).

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Improved sensors for application in dual-wavelength reflectance pulse oximetry have been developed. As disclosed in the following publication: Mendelson, et al., "Noninvasive pulse oximetry utilizing skin reflectance photoplethysmography", *IEEE Transactions on Biomedical Engineering*, vol. 35, no. 10, pp. 798-805 (1988), the total amount of backscattered light that can be detected by a reflectance sensor is directly proportional to the number of photodetectors placed around the LEDs. Additional improvements in signal-to-noise ratio were achieved by increasing the active area of the photodetector and optimizing the separation distance between the light sources and photodetectors.

Another approach is based on the use of a sensor having six photodiodes arranged symmetrically around the LEDs that is disclosed in the following publications:

4. Mendelson, et al., "Design and evaluation of a new reflectance pulse oximeter sensor", *Medical Instrumentation*, vol. 22, no. 4, pp. 167-173 (1988); and

5. Mendelson, et al., "Skin reflectance pulse oximetry: in vivo measurements from the forearm and calf", *Journal of Clinical Monitoring*, vol. 7, pp. 7-12, (1991).

According to this approach, in order to maximize the fraction of backscattered light collected by the sensor, the currents from all six photodiodes are summed electronically by internal circuitry in the pulse oximeter. This configuration essentially creates a large area photodetector made of six discrete photodiodes connected in parallel to produce a single current that is proportional to the amount of light backscattered from the skin. Several studies showed that this sensor configuration could be used successfully to accurately measure SaO_2 from the forehead, forearm and the calf on humans. However, this sensor requires a means for heating the skin in order to increase local blood flow, which has practical limitations since it could cause skin burns.

Yet another prototype reflectance sensor is based on eight dual-wavelength LEDs and a single photodiode, and is disclosed in the following publication: Takatani et al., "Experimental and clinical evaluation of a noninvasive reflectance pulse oximeter sensor", *Journal of Clinical Monitoring*, vol. 8, pp. 257-266 (1992). Here, four R and four IR LEDs are spaced at 90-degree intervals around the substrate and at an equal radial distance from the photodiode.

A similar sensor configuration based on six photodetectors mounted in the center of the sensor around the LEDs is disclosed in the following publication: Konig, et al., "Reflectance pulse oximetry—principles and obstetric application in the Zurich system", *Journal of Clinical Monitoring*, vol. 14, pp. 403-412 (1998).

According to the techniques disclosed in all of the above publications, only LEDs of two wavelengths, R and IR, are used as light sources, and the computation of SaO_2 is based on reflection photoplethysmograms measured by a single photodetector, regardless of whether one or multiple photodiodes chips are used to construct the sensor. This is because of the fact that the individual signals from the photodetector elements are all summed together electronically inside the pulse oximeter. Furthermore, while a radially-symmetric photodetector array can help to maximize the detection of backscattered light from the skin and minimize differences from local tissue inhomogeneity, human and animal studies confirmed that this configuration can not completely eliminate errors caused by pressure differences and site-to-site variations.

The use of a nominal dual-wavelength pair of 735/890 nm was suggested as providing the best choice for optimizing

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accuracy, as well as sensitivity in dual-wavelength reflectance pulse oximetry, in U.S. Pat. Nos. 5,782,237 and 5,421,329. This approach minimizes the effects of tissue heterogeneity and enables to obtain a balance in path length changes arising from perturbations in tissue absorbance. This is disclosed in the following publications:

6. Mannheimer at al., "Physio-optical considerations in the design of fetal pulse oximetry sensors", *European Journal of Obstetrics and Gynecology and Reproductive Biology*, vol. 72, suppl. 1, pp. S9-S19, (1997); and

7. Mannheimer at al., "Wavelength selection for low-saturation pulse oximetry", *IEEE Transactions on Biomedical Engineering*, vol. 44, no. 3, pp. 48-158 (1997)].

However, replacing the conventional R wavelength at 660 nm, which coincides with the region of the spectrum where the difference between the extinction coefficient of Hb and HbO₂ is maximal, with a wavelength emitting at 735 nm, not only lowers considerably the overall sensitivity of a pulse oximeter, but does not completely eliminate errors due to sensor placement and varying contact pressures.

Pulse oximeter probes of a type comprising three or more LEDs for filtering noise and monitoring other functions, such as carboxyhemoglobin or various indicator dyes injected into the blood stream, have been developed and are disclosed, for example, in WO 00/32099 and U.S. Pat. No. 5,842,981. The techniques disclosed in these publications are aimed at providing an improved method for direct digital signal formation from input signals produced by the sensor and for filtering noise.

None of the above prior art techniques provides a solution to overcome the most essential limitation in reflectance pulse oximetry, which requires the automatic correction of the internal calibration curve from which accurate and reproducible oxygen saturation values are derived, despite variations in contact pressure or site-to-site tissue heterogeneity.

In practice, most sensors used in reflection pulse oximetry rely on closely spaced LED wavelengths in order to minimize the differences in the optical path lengths of the different wavelengths. Nevertheless, within the wavelength range required for oximetry, even closely spaced LEDs with closely spaced wavelengths mounted on the same substrate can lead to large random error in the final determination of SaO₂.

SUMMARY OF THE INVENTION AND ADVANTAGES

The object of the invention is to provide a novel sensor design and method that functions to correct the calibration relationship of a reflectance pulse oximeter, and reduce measurement inaccuracies in general. Another object of the invention is to provide a novel sensor and method that functions to correct the calibration relationship of a reflectance pulse oximeter, and reduce measurement inaccuracies in the lower range of oxygen saturation values (typically below 70%), which is the predominant range in neonatal and fetal applications.

Yet another object of the present invention is to provide automatic correction of the internal calibration curve from which oxygen saturation is derived inside the oximeter in situations where variations in contact pressure or site-to-site tissue heterogeneity may cause large measurement inaccuracies.

Another object of the invention is to eliminate or reduce the effect of variations in the calibration of a reflectance

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pulse oximeter between subjects, since perturbations caused by contact pressure remain one of the major sources of errors in reflectance pulse oximetry. In fetal pulse oximetry, there are additional factors, which must be properly compensated for in order to produce an accurate and reliable measurement of oxygen saturation. For example, the fetal head is usually the presenting part, and is a rather easily accessible location for application of reflectance pulse oximetry. However, uterine contractions can cause large and unpredictable variations in the pressure exerted on the head and by the sensor on the skin, which can lead to large errors in the measurement of oxygen saturation by a dual-wavelength reflectance pulse oximeter. Another object of the invention is to provide accurate measurement of oxygen saturation in the fetus during delivery.

The basis for the errors in the oxygen saturation readings of a dual-wavelength pulse oximeter is the fact that, in practical situations, the reflectance sensor applications affect the distribution of blood in the superficial layers of the skin. This is different from an ideal situation, when a reflectance sensor measures light backscattered from a homogenous mixture of blood and bloodless tissue components. Therefore, the R and IR DC signals practically measured by photodetectors contain a relatively larger proportion of light absorbed by and reflected from the bloodless tissue compartments. In these uncontrollable practical situations, the changes caused are normally not compensated for automatically by calculating the normalized R/IR ratio since the AC portions of each photoplethysmogram, and the corresponding DC components, are affected differently by pressure or site-to-site variations. Furthermore, these changes depend not only on wavelength, but depend also on the sensor geometry, and thus cannot be eliminated completely by computing the normalized R/IR ratio, as is typically the case in dual-wavelength pulse oximeters.

The inventor has found that the net result of this nonlinear effect is to cause large variations in the slope of the calibration curves. Consequently, if these variations are not compensated automatically, they will cause large errors in the final computation of SpO₂, particularly at low oxygen saturation levels normally found in fetal applications.

Another object of the present invention is to compensate for these variations and to provide accurate measurement of oxygen saturation. The invention consists of, in addition to two measurement sessions typically carried out in pulse oximetry based on measurements with two wavelengths centered around the peak emission values of 660 nm (red spectrum) and 940 nm±20 nm (IR spectrum), one additional measurement session is carried out with an additional wavelength. At least one additional wavelength is preferably chosen to be substantially in the IR region of the electromagnetic spectrum, i.e., in the NIR-IR spectrum (having the peak emission value above 700 nm). In a preferred embodiment the use of at least three wavelengths enables the calculation of an at least one additional ratio formed by the combination of the two IR wavelengths, which is mostly dependent on changes in contact pressure or site-to-site variations. In a preferred embodiment, slight dependence of the ratio on variations in arterial oxygen saturation that may occur, is easily minimized or eliminated completely, by the proper selection and matching of the peak emission wavelengths and spectral characteristics of the at least two IR-light sources.

Preferably, the selection of the IR wavelengths is based on certain criteria. The IR wavelengths are selected to coincide with the region of the optical absorption curve where HbO₂ absorbs slightly more light than Hb. The IR wavelengths are

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in the spectral regions where the extinction coefficients of both Hb and HbO₂ are nearly equal and remain relatively constant as a function of wavelength, respectively.

In a preferred embodiment, tracking changes in the ratio formed by the two IR wavelengths, in real-time, permits automatic correction of errors in the normalized ratio obtained from the R-wavelength and each of the IR-wavelengths. The term "ratio" signifies the ratio of two values of AC/DC corresponding to two different wavelengths. This is similar to adding another equation to solve a problem with at least three unknowns (i.e., the relative concentrations of HbO₂ and Hb, which are used to calculate SaO₂, and the unknown variable fraction of blood-to-tissue volumes that effects the accurate determination of SaO₂), which otherwise must rely on only two equations in the case of only two wavelengths used in conventional dual-wavelength pulse oximetry. In a preferred embodiment, a third wavelength provides the added ability to compute SaO₂ based on the ratio formed from the R-wavelength and either of the IR-wavelengths. In a preferred embodiment, changes in these ratios are tracked and compared in real-time to determine which ratio produces a more stable or less noisy signal. That ratio is used predominantly for calculating SaO₂.

The present invention utilizes collection of light reflected from the measurement location at different detection locations arranged along a closed path around light emitting elements, which can be LEDs or laser sources. Preferably, these detection locations are arranged in two concentric rings, the so-called "near" and "far" rings, around the light emitting elements. This arrangement enables optimal positioning of the detectors for high quality measurements, and enables discrimination between photodetectors receiving "good" information (i.e., AC and DC values which would result in accurate calculations of SpO₂) and "bad" information (i.e., AC and DC values which would result in inaccurate calculations of SpO₂).

There is thus provided according to one aspect of the present invention, a sensor for use in an optical measurement device for non-invasive measurements of blood parameters, the sensor comprising:

(1) a light source for illuminating a measurement location with incident light of at least three wavelengths, the first wavelength lying in a red (R) spectrum, and the at least second and third wavelengths lying substantially in the infrared (IR) spectrum; and

(2) a detector assembly for detecting light returned from the illuminated location, the detector assembly being arranged so as to define a plurality of detection locations along at least one closed path around the light source.

The term "closed path" used herein signifies a closed curve, like a ring, ellipse, or polygon, and the like.

The detector assembly is comprised of at least one array of discrete detectors (e.g., photodiodes) accommodated along at least one closed path, or at least one continuous photodetector defining the closed path.

The term "substantially IR spectrum" used herein signifies a spectrum range including near infrared and infrared regions.

According to another aspect of the present invention, there is provided a pulse oximeter utilizing a sensor constructed as defined above, and a control unit for operating the sensor and analyzing data generated thereby.

According to yet another aspect of the present invention, there is provided a method for non-invasive determination of a blood parameter, the method comprising the steps of:

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illuminating a measurement location with at least three different wavelengths λ_1 , λ_2 and λ_3 , the first wavelength λ_1 lying in a red (R) spectrum, and the at least second and at least third wavelengths λ_2 and λ_3 lying substantially in the infrared (IR) spectrum;

detecting light returned from the measurement location at different detection locations and generating data indicative of the detected light, wherein said different detection locations are arranged so as to define at least one closed path around the measurement location; and

analyzing the generated data and determining the blood parameter.

BRIEF DESCRIPTION OF THE DRAWINGS

Other advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

FIG. 1 illustrates hemoglobin spectra as measured by oximetry based techniques;

FIG. 2 illustrates a calibration curve used in pulse oximetry as typically programmed by the pulse oximeters manufacturers;

FIG. 3 illustrates the relative disposition of light source and detector in reflection-mode or backscatter type pulse oximetry;

FIG. 4 illustrates light propagation in reflection pulse oximetry;

FIGS. 5A and 5B illustrate a pulse oximeter reflectance sensor operating under ideal and practical conditions, respectively;

FIG. 6 illustrates variations of the slopes of calibration curves in reflectance pulse oximetry measurements;

FIG. 7 illustrates an optical sensor according to the invention;

FIG. 8 is a block diagram of the main components of a pulse oximeter utilizing the sensor of FIG. 7;

FIG. 9 is a flow chart of a selection process used in the signal processing technique according to the invention; and

FIGS. 10A to 10C are flow charts of three main steps, respectively, of the signal processing method according to the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the Figures, wherein like numerals indicate like or corresponding parts throughout the several views, FIGS. 1 and 2 illustrate typical hemoglobin spectra and calibrations curve utilized in the pulse oximetry measurements.

The present invention provides a sensor for use in a reflection-mode or backscatter type pulse oximeter. The relative disposition of light source and detector in the reflection-mode pulse oximeter are illustrated in FIG. 3.

FIG. 4 shows light propagation in the reflection-mode pulse oximeter where, in addition to the optical absorption and reflection due to blood, the DC signal of the R and IR photoplethysmograms can be adversely affected by strong reflections from the bone.

FIGS. 5A and 5B illustrate a pulse oximeter reflectance sensor operating under, respectively, ideal and practical conditions. Referring now to FIG. 5A, it is shown that, under

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ideal conditions, reflectance sensor measures light backscattered from a homogenous mixture of blood and bloodless tissue components. Accordingly, the normalized R/IR ratio in dual-wavelength reflection type pulse oximeters, which relies on proportional changes in the AC and DC components in the photoplethysmograms, only reflect changes in arterial oxygen saturation.

Referring now to FIG. 5B, in practical situations, the sensor applications affect the distribution of blood in the superficial layers of the skin. Accordingly, the R and IR DC signals measured by photodetectors contain a relatively larger proportion of light absorbed by and reflected from the bloodless tissue compartments. As such, the changes in DC signals depend not only on wavelength but also sensor geometry and thus cannot be eliminated completely by computing the normalized R/IR ratio, as is typically the case in dual-wavelength pulse oximeters. The result is large variations in the slope of the calibration curves, as illustrated in FIG. 6. Referring now to FIG. 6, graphs C1, C2 and C3 show three calibration curves, presenting the variation of the slope for oxygen saturation values between 50% and 100%.

Referring to FIG. 7, there is illustrated an optical sensor 10 designed according to the invention aimed at minimizing some of the measurement inaccuracies in a reflectance pulse oximeter. The sensor 10 comprises such main constructional parts as a light source 12 composed of three closely spaced light emitting elements (e.g., LEDs or laser sources) 12a, 12b and 12c generating light of three different wavelengths, respectively; an array of discrete detectors (e.g., photodiodes), a "far" detector 16 and a "near" detector 18, arranged in two concentric ring-like arrangements (constituting closed paths) surrounding the light emitting elements; and a light shield 14. In the present example, six photodiodes form each ring. All these elements are accommodated in a sensor housing 17. The light shield 14 is positioned between the photodiodes and the light emitting elements, and prevents direct optical coupling between them, thereby maximizing the fraction of backscattered light passing through the arterially perfused vascular tissue in the detected light.

It should be noted that more than three wavelengths can be utilized in the sensor. The actual numbers of wavelengths used as a light source and the number of photodetectors in each ring are not limited and depend only on the electronic circuitry inside the oximeter. The array of discrete photodiodes can be replaced by one or more continuous photodetector rings.

In addition to the R and IR light emitting elements 12a and 12b as used in the conventional pulse oximeter sensors, the sensor 10 incorporates the third, reference, light emitting element 12c, which emits light in the NIR-IR spectrum. Wavelength λ_1 and λ_2 of the R and IR light emitting elements 12a and 12b are centered, respectively, around the peak emission values of 660 nm and 940 nm, and wavelength λ_3 of the third light emitting element 12c has the peak emission value above 700 nm (typically ranging between 800 nm and 900 nm). In the description below, the light emitting elements 12b and 12c are referred to as two IR light emitting elements, and wavelengths λ_2 and λ_3 are referred to as two IR wavelengths.

During the operation of the sensor 10, different light emitting elements are selectively operated for illuminating a measurement location (not shown) with different wavelengths. Each of the photodetectors detects reflected light of different wavelengths and generates data indicative of the intensity I of the detected light of different wavelengths.

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It should be noted that the sensor can be of a compact design utilizing an integrated circuit manufactured by CMOS technology. This technique is disclosed in a co-pending application assigned to the assignee of the present application. According to this technique, the sensor comprises a package including the light source, a block of two tubular optical waveguides of different diameters concentrically dislocated one inside the other and surrounding the light source, and an integrated circuit plate comprising two ring-like areas of photodiodes positioned concentrically one inside the other. The integrated circuit is also provided with a plurality of printed contact areas and electric conductors intended for mounting the light source thereon, controlling the light source, and transmitting electric signals produced by the photodiodes areas for further processing.

FIG. 8 illustrates a block diagram of a pulse oximeter 20 utilizing the above-described sensor 10. The pulse oximeter typically includes a control unit 21, which is composed of an electronic block 22 including A/D and D/A converters connectable to the sensor 10, a microprocessor 24 for analyzing measured data, and a display 26 for presenting measurement results. The measured data (i.e., electrical output of the sensor 10 indicative of the detected light) is directly processed in the block 22, and the converted signal is further processed by the microprocessor 24. The microprocessor 24 is operated by a suitable software model for analyzing the measured data and utilizing reference data (i.e., calibration curve stored in a memory) to compute the oxygen saturation value, which is then presented on the display 26. The analysis of the measured data utilizes the determination of AC- and DC-components in the detected light for each wavelength, λ_1 , λ_2 , and λ_3 , respectively, i.e., $I_1^{(AC)}$, $I_1^{(DC)}$, $I_2^{(AC)}$, $I_2^{(DC)}$, $I_3^{(AC)}$, and $I_3^{(DC)}$, and the calculation of AC/DC ratio for each wavelength, namely, $W_1 = I_1^{(AC)}/I_1^{(DC)}$, $W_2 = I_2^{(AC)}/I_2^{(DC)}$, and $W_3 = I_3^{(AC)}/I_3^{(DC)}$, as will be described more specifically further below with reference to FIGS. 9 and 10A-10C.

The pulse oximeter 20 with the sensor arrangement shown in FIG. 7 provides the following three possible ratio values: W_1/W_2 , W_1/W_3 and W_2/W_3 . It should be noted that W_1/W_2 and W_1/W_3 are the ratios that typically have the highest sensitivity to oxygen saturation. This is due to the fact that λ_1 is chosen in the red region of the electromagnetic spectrum, where the changes in the absorption between Hb and HbO₂ are the largest, as described above with reference to FIG. 1. Therefore, in principle, the absorption ratios formed by either wavelength pair λ_1 and λ_2 or wavelength pair λ_1 and λ_3 can be used to compute the value of SaO₂.

The inventor conducted extensive human and animal studies, and confirmed that either of the two ratios W_1/W_2 and W_1/W_3 can be affected not only by changes in arterial oxygen saturation, but also by sensor placement and by the amount of pressure applied by the sensor on the skin. Any calculation of SaO₂ based on either of the two ratios W_1/W_2 and W_1/W_3 alone (as normally done in commercially available dual-wavelength pulse oximeters) could result in significant errors. Furthermore, since at least two wavelengths are necessary for the calculation of arterial oxygen saturation, it is not feasible to self-correct the calibration curve for variations due to contact pressure or site-to-site variations utilizing the same two wavelengths used already to compute SaO₂.

The inventor has found that the third ratio W_2/W_3 formed by the combination of the two IR wavelengths is mostly dependent on changes in contact pressure or site-to-site variations. Furthermore, this ratio can depend, but to a much lesser degree, on variations in arterial oxygen saturation.

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The dependency on arterial oxygen saturation, however, is easily minimized or eliminated completely, for example by selection and matching of the peak emission wavelengths and spectral characteristics of the two IR light emitting elements 12b and 12c.

Generally, the two IR wavelengths λ_2 and λ_3 are selected to coincide with the region of the optical absorption curve where HbO₂ absorbs slightly more light than Hb, but in the spectral region, respectively, where the extinction coefficients of both Hb and HbO₂ are nearly equal and remain relatively constant as a function of wavelength. For example, at 940 nm and 880 nm, the optical extinction coefficients of Hb and HbO₂ are approximately equal to 0.29 and 0.21, respectively. Therefore, ideally, the ratio of W2/W3 should be close to 1, except for situations when the AC/DC signals measured from λ_2 and λ_3 are affected unequally causing the ratio W2/W3 to deviate from 1.

Fortunately, variations in the ratio W2/W3 mimic changes in the ratios W₁/W₂ and W₁/W₃ since these ratios are all affected by similar variations in sensor positioning or other uncontrollable factors that normally can cause large errors in the calibration curve from which oxygen saturation is typically derived. Thus, by tracking in real-time changes in the ratio formed by wavelengths λ_2 and λ_3 , it is possible to automatically correct for errors in the normalized ratios obtained from wavelengths λ_1 and λ_2 , or from λ_1 and λ_3 .

The use of an additional third wavelength in the sensor serves another important function (not available in conventional dual-wavelength pulse oximeters), which is associated with the following. Reflectance pulse oximeters have to be capable of detecting and relying on the processing of relatively low quality photoplethysmographic signals. Accordingly, electronic or optical noise can cause large inaccuracies in the final computation of SaO₂. Although the amount of electronic or optical noise pickup from the sensor can be minimized to some extent, it is impossible to render the signals measured by the pulse oximeter completely noise free. Therefore, pulse oximeters rely on the assumption that any noise picked up during the measurement would be cancelled by calculating the ratio between the R- and IR-light intensities measured by the photodetector. Practically, however, the amount of noise that is superimposed on the R- and IR-photoplethysmograms cannot be cancelled completely and, thus, can lead to significant errors in the final computation of SaO₂ which, in dual-wavelength pulse oximeters, is based only on the ratio between two wavelengths.

By utilizing a third wavelength, the invention has the added ability to compute SaO₂ based on the ratio formed from either W₁/W₂ or W₁/W₃. An algorithm utilized in the pulse oximeter according to the invention has the ability to track and compare in real-time changes between W₁/W₂ and W₁/W₃ to determine which ratio produces a more stable or less noisy signal and selectively choose the best ratio for calculating SaO₂.

The method according to the invention utilizes the so-called "selection process" as part of the signal processing technique based on the measured data obtained with the multiple photodetectors. The main steps of the selection process are shown in FIG. 9 in a self-explanatory manner. Here, the symbol *i* corresponds to a single photodetector element in the array of multiple discrete photodetector elements, the term "1st" signifies the last photodetector element in the array, and the term "DATA" signify three ratios (AC/DC) computed separately for each of the three wavelengths, namely, W₁, W₂ and W₃.

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The selection process is associated with the following: Practically, each time one of the light emitting elements is in its operative position (i.e., switched on), all of the photodetectors in the sensor receiving backscattered light from the skin. However, the intensity of the backscattered light measured by each photodetector may be different from that measured by the other photodetectors, depending on the anatomical structures underneath the sensor and its orientation relative to these structures.

Thus, the selection process is used to discriminate between photodetectors receiving "good" signals (i.e., "good" signal meaning that the calculation of SpO₂ from the pulsating portion of the electro-optic signal (AC) and the constant portion (DC) would result in accurate value) and "bad" signals (i.e., having AC and DC values which would result in inaccurate calculations of SpO₂). Accordingly, each data point (i.e., ratio W_{1i}, W_{2i} or W_{3i} detected at the corresponding *i*th detector) is either accepted, if it meets a certain criteria based for example on a certain ratio of AC to DC values (e.g., such that the intensity of AC signal is about 0.05–2.0% of the intensity of DC signal), or rejected. All of the accepted data points (data from accepted detection locations) are then used to calculate the ratios W₁/W₂, W₁/W₃ and W₂/W₃, and to calculate the SpO₂ value, in conjunction with the signal processing technique, as will be described further below with reference to FIGS. 10A–10C.

Besides the use of the third IR-wavelength to compensate for changes in the internal calibration curve of the pulse oximeter, the pulse oximeter utilizing the sensor according to the invention provides a unique new method to compensate for errors due to sensor positioning and pressure variability. This method is based on multiple photodetector elements, instead of the conventional approach that relies on a single photodetector.

While optical sensors with multiple photodetectors for application in reflectance pulse oximetry have been described before, their main limitation relates to the way the information derived from these photodetectors is processed. Although the primary purpose of utilizing multiple photodetectors is to collect a larger portion of the backscattered light from the skin, practically, summing the individual intensities of each photodetector and using the resulting value to compute SaO₂ can introduce large errors into the calculations. These errors can be caused, for example, by situations where the sensor is placed over inhomogeneous tissue structures such as when the sensor is mounted on the chest. The case may be such that, when using a continuous photodetector ring to collect the backscattered light, a portion of the photodetector ring lies over a rib, which acts as a strongly reflecting structure that contributes to a strong DC component, and the remaining part of the photodetector is positioned over the intercostals space, where the DC signal is much smaller. In this case, the final calculation of SaO₂ would be inaccurate, if the current produced by this photodetector is used indiscriminately to compute the DC value before the final computation of SaO₂ is performed. Therefore, in addition to automatically correcting errors in the calibration curve as outlined above using three different LEDs (one R and two different IR wavelengths), the sensor 10 has the optional ability to track automatically and compare changes in the R/IR ratios obtained from each of the discrete photodiodes individually. For example, if some of either the near or the far photodetectors in the two concentrically arranged arrays detect larger than normal DC signals during the operation of one of the photodiodes compared to the other photodiodes in the sensor, it could be indicative of one of the following situations: the sensor is positioned

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unevenly, the sensor is partially covering a bony structure, or uneven pressure is exerted by the sensor on the skin causing partial skin “blanching” and therefore the blood-to-bloodless tissue ratio might be too high to allow accurate determination of SaO_2 . If such a situation is detected, the oximeter has the ability to selectively disregard the readings obtained from the corresponding photodetectors. Otherwise, if the DC and AC signals measured from each photodetector in the array are similar in magnitude, which is an indication that the sensor is positioned over a homogeneous area on the skin, the final computation of SaO_2 can be based on equal contributions from every photodetector in the array.

Turning now to FIGS. 10A, 10B and 10C, there are illustrated three main steps of the signal processing technique utilized in the present invention. Here, TH_1 and TH_2 are two different threshold values (determined experimentally) related respectively to W_2/W_3 and $(W_1/W_2 - W_1/W_3)$.

During step 1 (FIG. 10A), measured data generated by the “near” and “far” photodetectors indicative of the detected (backscattered) light of wavelength λ_2 and λ_3 is analyzed to calculate the two ratios W_2/W_3 (far and near). If one of the calculated ratios (far or near) is not in the range of $1 \pm \text{TH}_1$ (TH_1 is for example 0.1), then this data point is rejected from the SpO_2 calculation, but if both of them are not in the mentioned range, a corresponding alarm is generated indicative of that the sensor position should be adjusted. Only if there are calculated ratios which are in the range of $1 \pm \text{TH}_1$, they are accepted and the process (data analysis) proceeds by performing step 2.

Step 2 (FIG. 10B) consists of determining whether the quality of each photoplethysmogram is acceptable or not. The quality determination is based on the relative magnitude of each AC component compared to its corresponding DC component. If the quality is not acceptable (e.g., the signal shape detected by any detector varies within a time frame of the measurement session, which may for example be 3.5 sec), the data point is rejected and a corresponding alarm signal is generated. If the AC/DC ratio of W_1 , W_2 and W_3 are within an acceptable range, the respective data point is accepted, and the process proceeds through performing step 3.

In step 3 (FIG. 10C), the measured data is analyzed to calculate ratios W_1/W_2 and W_1/W_3 from data generated by far and near photodetectors, and to calculate the differences $(W_1/W_2 - W_1/W_3)$.

In a perfect situation, W_1/W_2 (far) is very close to W_1/W_3 (far), and W_1/W_2 (near) is very close to W_1/W_3 (near). In a practical situation, this condition is not precisely satisfied, but all the ratios are close to each other if the measurement situation is “good”.

Then, the calculated differences are analyzed to determine the values (corresponding to far and near photodetectors) that are accepted and to use them in the SpO_2 calculation. For each detector that satisfied the condition $\text{ABS}(W_1/W_2 - W_1/W_3) < \text{TH}_2$, where ABS signifies the absolute value, its respective data point is accepted and used to calculate the oxygen saturation value that will be displayed. If the condition is not satisfied, the data point is rejected. If all data points are rejected, another measurement session is carried out.

It should be noted that, although the steps 1–3 above are exemplified with respect to signal detection by both near and far photodetectors, each of these steps can be implemented by utilizing only one array of detection locations along the closed path. The provision of two such arrays, however, provides higher accuracy of measurements.

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ELEMENT LIST

- 10 optical sensor
- 12 light source
- 12a LED
- 12b LED
- 12c LED
- 13 detector assembly
- 14 light shield
- 15 array of detectors
- 16 far detector
- 17 sensor housing
- 18 near detector
- 20 pulse oximeter
- 21 control unit
- 22 electronic block
- 24 microprocessor
- 26 display

What is claimed is:

1. A method for non-invasive determination of a blood parameter, the method comprising the steps of:

- (i) illuminating a measurement location with at least three different wavelengths, a first wavelength λ_1 lying in a red (R) spectrum, and at least second and third wavelengths λ_2 and λ_3 lying substantially in the infrared (IR) spectrum;
- (ii) detecting light returned from the measurement location at different detection locations and generating data indicative of the detected light for the different detection locations, wherein said different detection locations are arranged so as to define at least one closed path around the measurement location; and
- (iii) analyzing the generated data and determining the blood parameter.

2. The method according to claim 1, wherein the analysis of the generated data comprises the steps of:

- calculating data indicative of an AC/DC ratio in the light detected at each of the detection locations for the at least three wavelengths;
- analyzing the calculated data and determining accepted detection locations to select corresponding AC/DC ratios for each of the at least three wavelengths, λ_1 , λ_2 and λ_3 ; and

utilizing the selected ratios for determining the blood parameter.

3. The method according to claim 2, wherein the determination of the blood parameter comprises the steps of:

- calculating values of the ratio W_2/W_3 for the accepted detection locations in at least one closed path;
- analyzing each of the calculated values to determine whether it satisfies a first predetermined condition, so as to generate a signal indicative of that a sensor position is to be adjusted, if the condition is not satisfied;
- if the condition is satisfied, determining whether the quality of a photoplethysmogram is acceptable;
- if the quality is acceptable, analyzing the selected ratios for calculating ratios W_1/W_2 and W_1/W_3 from the data detected in at least one closed path, and calculating the differences $\text{ABS}(W_1/W_2 - W_1/W_3)$; and,

analyzing the calculated differences for determining whether each of the differences satisfies a second predetermined condition for determining the blood parameter if the condition is satisfied.

4. The method according to claim 3, wherein said first predetermined condition consists of that the calculated value

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of $W2/W3$ is inside a predetermined range around the value one, said predeteonined range being defined by the first threshold value, and the second predetermined condition consists of that the calculated difference $ABS(W1/W2 - W1/W3)$ is less than certain, second threshold value.

5 5. A method for non-invasive determination of a blood parameter, the method comprising the steps of:

illuminating a measurement location with at least three different wavelengths, a first wavelength $\lambda1$ lying in a red (R) spectrum, and at least second and third wave- 10 lengths $\lambda2$ and $\lambda3$ lying substantially in the infrared (IR) spectrum;

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detecting light returned from the measurement location at different detection locations and generating data indicative of the detected light for the different detection locations, wherein said different detection locations are arranged so as to define at least one closed path around the measurement location;

calculating data indicative of an AC/DC ratio in the light detected at each of the detection locations for the at least three wavelengths; and, analyzing the calculated data and determining the blood parameter.

* * * * *

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Poeze et al.
U.S. Patent No.: 10,299,708 Attorney Docket No.: 50095-0009IP1
Issue Date: May 28, 2019
Appl. Serial No.: 16/261,366
Filing Date: May 10, 2019
Title: MULTI-STREAM DATA COLLECTION SYSTEM
FOR NONINVASIVE MEASUREMENT OF
BLOOD CONSTITUENTS

SECOND DECLARATION OF DR. THOMAS W. KENNY

I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of the Title 18 of the United States Code.

Dated: November 19, 2021

By: _____



Thomas W. Kenny, Ph.D.

I. Introduction

1. I have been retained on behalf of Apple Inc. to offer technical opinions relating to U.S. Patent No. 10,299,708 (“the ’708 Patent”) in the present case (IPR2021-00193). In this Second Declaration, I provide opinions related to Patent Owner’s Response (Paper 14) and Dr. Madisetti’s supporting declaration (Ex. 2004).

2. In addition to the materials listed in my First Declaration (APPLE-1003), I have reviewed several additional documents and references including:

- Paper 7: Institution Decision;
- Paper 14: Patent Owner’s Response (“POR”);
- Ex. 2004: Declaration of Dr. Madisetti;
- Ex. 2006-2009: Transcripts of my prior depositions;
- APPLE-1034: Deposition Transcript of Dr. Vijay Madisetti in IPR2020- 01520, IPR2020-01537, IPR2020-01539, Day 1 (August 1, 2021);
- APPLE-1035: Deposition Transcript of Dr. Vijay Madisetti in IPR2020- 01520, IPR2020-01537, IPR2020-01539, Day 2 (August 2, 2021);
- APPLE-1036: Deposition Transcript of Dr. Vijay Madisetti in IPR2020- 01536, IPR2020-01538 (August 3, 2021);
- APPLE-1044: “Refractive Indices of Human Skin Tissues at Eight Wavelengths and Estimated Dispersion Relations between 300 and

4. I have no financial interest in the party or in the outcome of this proceeding. I am being compensated for my work as an expert on an hourly basis. My compensation is not dependent on the outcome of these proceedings or the content of my opinions.

5. In writing this declaration, I have considered the following: my own knowledge and experience, including my work experience in the fields of mechanical engineering, computer science, biomedical engineering, and electrical engineer; my experience in teaching those subjects; and my experience in working with others involved in those fields. In addition, I have analyzed various publications and materials, in addition to other materials I cite in my declaration.

6. My opinions, as explained below, are based on my education, experience, and expertise in the fields relating to the '708 Patent. Unless otherwise stated, my testimony below refers to the knowledge of one of ordinary skill in the fields as of the Critical Date, or before.

II. Ground 1 Establishes Obviousness

A. Inokawa's lens enhances the light-gathering ability of Aizawa

7. As I previously explained in the Original Declaration, Inokawa *very generally* describes a "lens [that] makes it possible to increase the light-gathering ability" of a reflectance type pulse sensor, APPLE-1008, [0015], [0058], FIG. 2, and, based on this disclosure, a POSITA would have been motivated to incorporate "an Inokawa-like lens into the cover of Aizawa to increase the light collection efficiency...." APPLE-1003, ¶¶84-88. In a significant extrapolation from the very simple and

purely illustrative description in Inokawa, Patent Owner provides two incorrect arguments. First, Patent Owner claims that Inokawa's disclosure is narrowly-limited to a particular lens that somehow is only capable of operation with peripheral emitters and a central detector. Second, the Patent Owner claims that the lens of Inokawa directs all incoming light rays "to the center of the sensor" and would "direct light *away* from the *periphery*-located detectors as in Aizawa," regardless of the direction of light propagation of each ray, which is a violation of elementary laws of light propagation that would be familiar to a POSITA. POR, 15, 20; *see also* APPLE-1034, 40:4-11 ("...as I describe in my Declaration...if you have a convex surface...*all light reflected* or otherwise would be condensed or directed towards the center."). Based on these two incorrect claims, the Patent Owner insists that there would be no motivation to combine.

8. Patent Owner's misinformed understanding of Inokawa's lens as well as lenses in general is demonstrated by their description of Inokawa's lens 27 as "focus[ing] light from LEDs (21, 23)...*to a single detector (25) in the center*" and "direct[ing] incoming light *to the centrally located detector*." POR, 12; *see also* APPLE-1034, 40:4-11 ("...as I describe in my Declaration...if you have a convex surface...*all light reflected* or otherwise would be condensed or directed towards the center.").

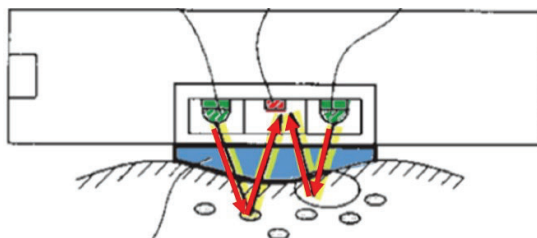
9. A correct understanding of Inokawa's lens as well as of reflectance type pulse sensors in general (like those disclosed by each of Aizawa, Inokawa, and Mendelson-1988) readily exposes Patent Owner's flawed rationale. Indeed, as I noted during

deposition, a POSITA would understand that Inokawa's lens generally improves "light concentration at pretty much all of the locations under the curvature of the lens," as opposed to only at a single point at the center as asserted by Patent Owner. Ex. 2006, 164:8-16. Indeed, as further explained below, a POSITA would have understood the following to be true—that a cover featuring a convex protrusion would improve Aizawa's signal-to-noise ratio by causing more light backscattered from tissue to strike Aizawa's photodetectors than would have with a flat cover. APPLE-1051, 52, 86, 90; APPLE-1052, 84, 87-92, 135-141; APPLE-1046, 803-805; APPLE-1006, FIGS. 1(a)-1(b). The convex cover enhances the light-gathering ability of Aizawa's sensor.

i. Masimo ignores the well-known principle of reversibility

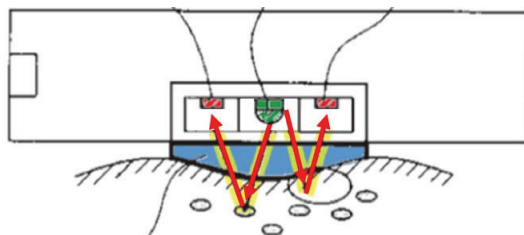
10. The well-known optical *principle of reversibility* readily dispels Masimo's claim that "a convex cover condenses light towards the center of the sensor and away from the periphery," when applied to Aizawa. POR, 15; APPLE-1052, 87-92; APPLE-1049, 106-111. Specifically, according to the principle of reversibility, "a ray going from P to S will trace the same route as one from S to P." APPLE-1052, 92, 84; APPLE-1049, 101, 110; APPLE-1036, 80:20-82:20. Importantly, the principle dictates that rays that are not completely absorbed by user tissue will propagate in a reversible manner. In other words, every ray that completes a path through tissue from an LED to a detector would trace an identical path through that tissue in reverse, if the positions of the LED emitting the ray and the receiving detector were swapped.

APPLE-1052, 92. To help explain, I have annotated Inokawa's FIG. 2 (presented below) to illustrate the principle of reversibility applied in the context of a reflective optical physiological monitor. As shown, Inokawa's FIG. 2, illustrates two example ray paths from surrounding LEDs (green) to a central detector (red):



APPLE-1008, FIG. 2 (annotated)

11. As a consequence of the principle of reversibility, a POSITA would have understood that if the LED/detector configuration were swapped, as in Aizawa, the two example rays would travel identical paths in reverse, from a central LED (red) to surrounding detectors (green). A POSITA would have understood that, for these rays, any condensing/directing/focusing benefit achieved by Inokawa's cover (blue) under the original configuration would be identically achieved under the reversed configuration:



APPLE-1008, FIG. 2 (annotated)

12. When factoring in additional scattering that may occur when light is reflected within human tissue, reversibility holds for each of the rays that are not completely absorbed; consequently, "if we're concerned with the impact of the lens on the system,

it's absolutely reversible." EX. 2006, 209:19-21, 207:9-209:21 ("one could look at any particular randomly scattered path...and the reversibility principle applies to all of the pieces [of that path] and, therefore, applies to the aggregate").

13. An example of reversibility in a situation with diffuse light, such as is present when LEDs illuminate tissue, is shown below from Hecht's Figure 4.12.

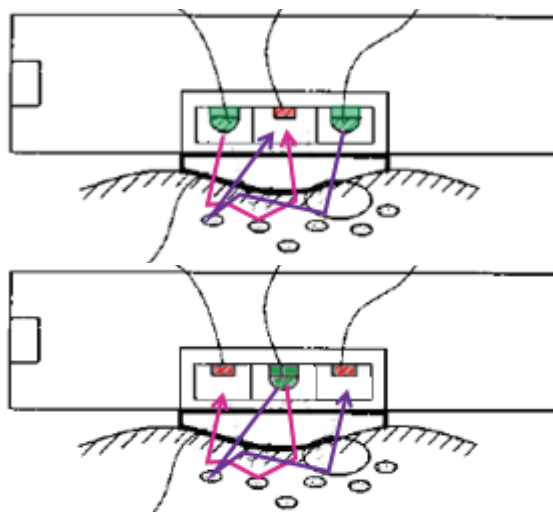


Figure 4.12 (a) Specular reflection. (b) Diffuse reflection. (Photos courtesy Donald Dunitz.)

14. In this figure 4.12a, collimated light is incident on a smooth surface, and exhibits specular reflection, in which parallel light rays encounter and are reflected from the surface and remain parallel. A POSITA would certainly understand specular reflection. In the case of the reflection as shown in Figure 4.12b, the random roughness of the surface scatters the incoming rays into many directions, and the resulting light would appear to be diffuse. However, even in this circumstance, the principle of reversibility applies—each individual ray can be reversed such that a ray travelling to the surface and scattered in a random direction can be followed backwards along exactly the same path.

15. In more detail, and as shown with respect to the example paths illustrated below (which include scattering within tissue), each of the countless photons

travelling through the system must abide by Fermat's principle. APPLE-1049, 106-111. Consequently, even when accounting for various random redirections and partial absorptions, each photon traveling between a detector and an LED would take the quickest (and identical) path along the segments between each scattering event, even if the positions of the detector and LED were swapped.



16. To better understand the effect of a convex lens on the propagation of light rays towards or away from the different LEDs or detectors, the first and last segment of the light path may be representative of the light propagation of the various light rays. In the figures above, starting at the upper left, there is a pink-colored light ray emerging from the green LED and passing through the convex lens and entering the tissue. On the lower left, there is a pink-colored light ray leaving the tissue and entering the convex lens. As drawn, these rays are the same in position and orientation, except that the direction is exactly reversed. This illustration is consistent with the Principle of Reversibility as applied to this pair of possible light rays.

According to the principle of reversibility, the upper light path from the LED to the

first interaction with a corpuscle is exactly reversed. This same behavioral pattern applies to all of the segments of the many light paths that cross the interface at the surface of the convex lens. Importantly, in this example, the convex lens does not refract the incoming ray in a different direction from the outgoing ray, e.g., in a direction towards the center different from the outgoing ray. As required by the principle of reversibility, this incoming ray follows the same path as the outgoing ray, except in the reverse direction. This statement is true for every segment of these light paths that crosses the interface between the tissue and the convex lens. Any ray of light that successfully traverses a path from the LED to the detector, that path already accounts for the random scattering as that scattering is what allowed the ray to go from the LED to a detector along the path to thereby be subsequently detected by the detector. A POSITA would have understood that the path is an aggregation of multiple segments and that the path is reversible as each of its segments would be reversible, consistent with Fermat's principle.

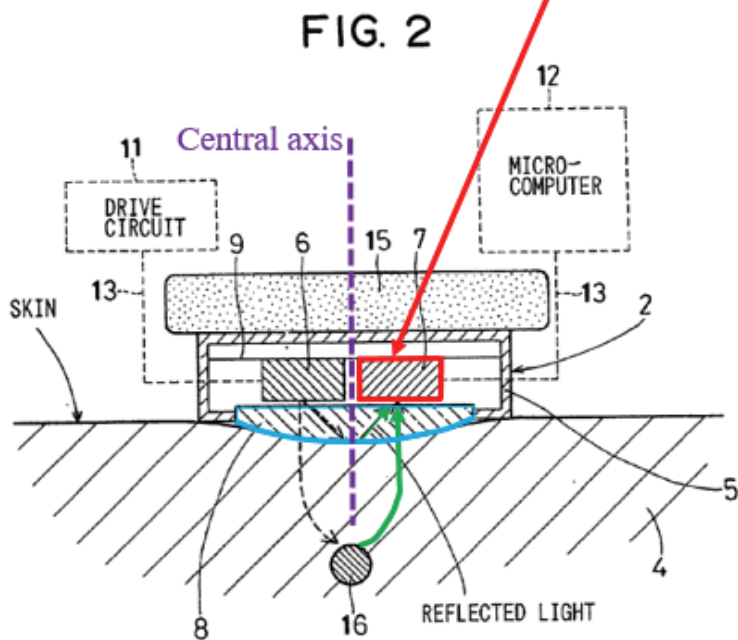
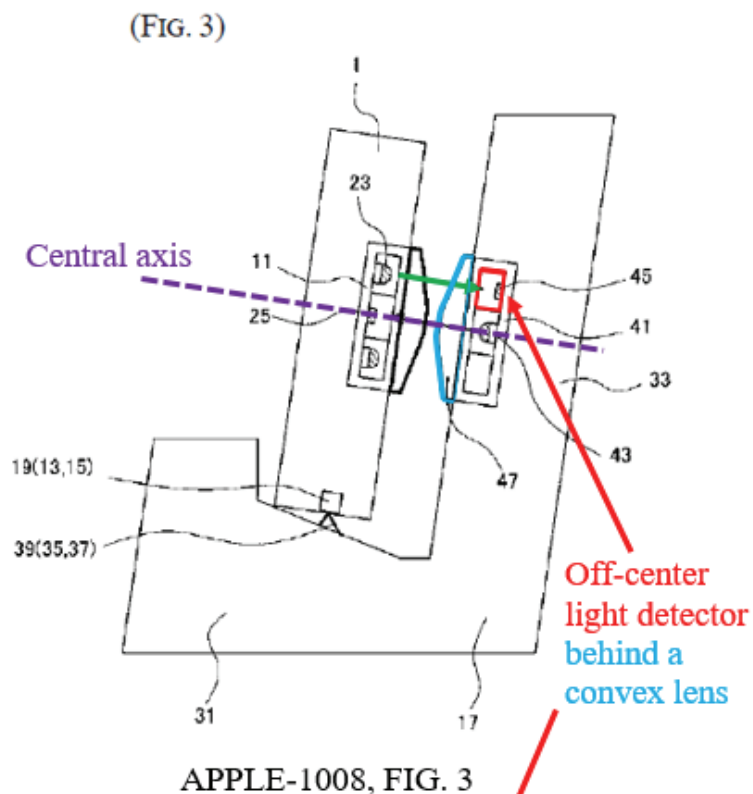
17. The statement about the reversibility of the segments of the light path which cross the interface between tissue and convex lens is consistent with the well-known and well-established Snell's law, which provides a simple algebraic relation between the angles of incidence and refraction as determined by the two indices of refraction. And Snell's law supports the basic understanding that the path of the light rays to/from a scattering event across the interface to/from the convex lens and on to/from the LED or photodetector must be reversible.

18. Based on this understanding of light rays and Snell's law, a POSITA would have understood that the positions of the emitters and detectors can be swapped in the proposed combination, and that the light paths from the initial situation would be reversed in the altered situation.

19. When confronted with this basic principle of reversibility during deposition, Dr. Madisetti refused to acknowledge it, even going so far as to express ignorance of "Fermat's principle, *whatever that is*." APPLE-1034, 89:12-19. Yet Fermat's principle, which states that a path taken by a light ray between two points is one that can be traveled in the least time, regardless of the direction of travel, is one of the most fundamental concepts in optics/physics and plainly requires the basic principle of reversibility. APPLE-1052, 87-92; APPLE-1049, 106-111. This is in no way a new theory, as this core concept dates back many years, and is offered in Aizawa itself. Indeed, *Aizawa recognizes this reversibility*, stating that while the configurations depicted include a central emitter surrounded by detectors, the "same effect can be obtained when...a plurality of light emitting diodes 21 are disposed around the photodetector 22." APPLE-1006, [0033]; EX. 2006, 209:19-21.

20. Masimo's technically and factually flawed argument is exposed by multiple prior art references, including the Ohsaki and Inokawa references which are the key elements of our combinations. As shown in the figures below, Ohsaki and Inokawa both show embodiments which use a convex lens to direct light to detectors that are not located at the center of a sensor. APPLE-1014, FIG. 2; APPLE-1008, FIG. 3.

In Inokawa's Figure 2, an off-center emitter and sensor are configured to send and receive text messages, and are capable of success, even though the detector is not positioned at the center.



APPLE-1014, FIG. 2

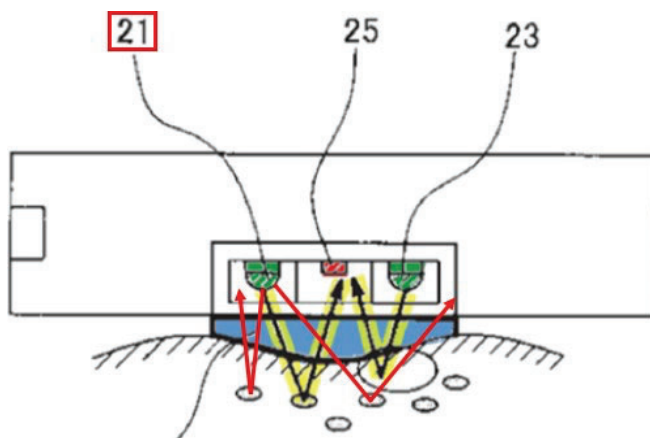
21. If, as asserted by the Patent Owner, a convex lens is required to condense, direct, or focus the light to the center, the embodiments disclosed by Ohsaki and Inokawa would all fail because there is no detector at the center to detect all of the light that would be directed towards the center by the convex board. The Ohsaki and Inokawa embodiments (reproduced above) do not show or otherwise teach that its convex board directs all light towards the center.

22. In short, based at least on the principle of reversibility, a POSITA would have understood that both configurations of LEDs and detectors—*i.e.*, with the LED at the center as in Aizawa or with the detector at the center as in Inokawa—would identically benefit from the enhanced light-gathering ability of a convex lens/protrusion.

ii. Masimo ignores the behavior of scattered light in a reflectance-type pulse sensor

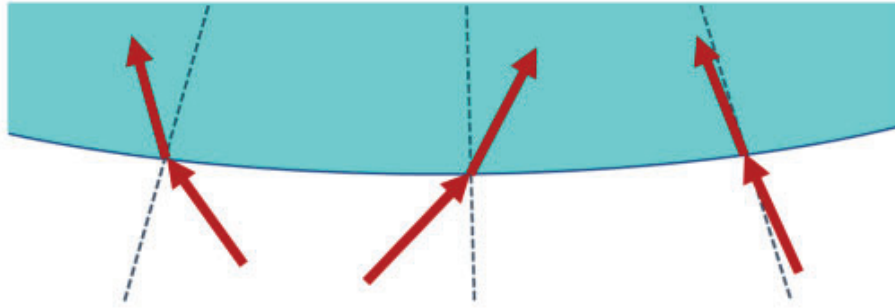
23. Because Aizawa is a reflectance-type pulse sensor that receives diffuse, backscattered light from the measurement site, its cover/lens cannot focus all incoming light toward the sensor's center. Ex. 2006, 163:12-164:2 (“A lens in general...doesn't produce a single focal point”). Indeed, reflectance-type sensors work by detecting light that has been “partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector.” APPLE-1051, 86. A POSITA would have understood that light which backscatters from the measurement site after diffusing through tissue reaches the active detection area from various random directions and angles. APPLE-1046, 803; APPLE-1051, 90, 52.

24. As noted above, basic law of refraction, namely Snell's law, dictates this behavior of light. APPLE-1052, 84; APPLE-1049, 101; APPLE-1036, 80:20-82:20; APPLE-1051, 52, 86, 90. For example, referring to Masimo's version of Inokawa's FIG. 2, further annotated below to show additional rays of light emitted from LED 21, it is clearly seen how some of the reflected/scattered light from the measurement site does not reach Inokawa's centrally located detector:



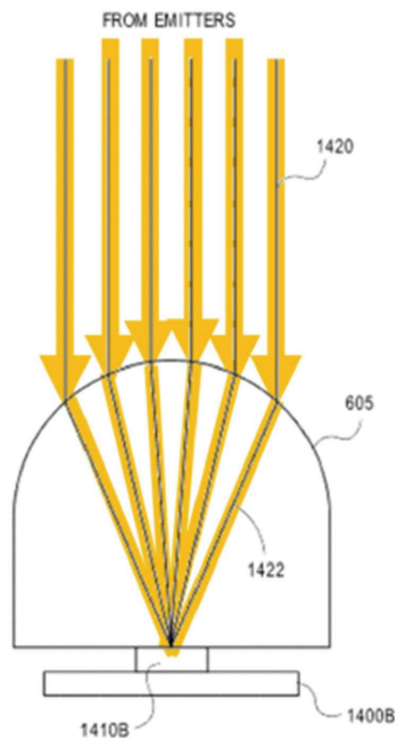
APPLE-1008, FIG. 2 (annotated); POR, 11.

25. For these and countless other rays that are not shown, there is simply no way for a cover to focus all light at the center of the sensor device. APPLE-1052, 84; APPLE-1049, 101; APPLE-1036, 80:20-82:20. The illustration I provide below shows how Snell's law determines a direction of a backscattered ray within a convex cover, thus providing a stark contrast to Masimo's assertions that all such rays must be redirected to or towards the center:



26. Indeed, far from focusing light to the center as Masimo contends, Ohsaki's convex cover provides a slight refracting effect, such that light rays that may have otherwise missed the detection area are instead directed toward that area as they pass through the interface provided by the cover. This is particularly true in configurations like Aizawa's in which light detectors are arranged symmetrically about a central light source, so as to enable backscattered light to be detected within a circular active detection area surrounding that source. APPLE-1051, 86, 90. The slight refracting effect is a consequence of the similar indices of refraction between human tissue and a typical cover material (e.g., acrylic). APPLE-1044, 1486; APPLE-1045, 1484).

27. To support the misguided notion that a convex cover focuses all incoming light at the center, Masimo relies heavily on the '708 Patent's FIG. 14B (reproduced below):



APPLE-1001, FIG. 14B (as annotated at POR, 24)

28. Masimo and Dr. Madisetti treat this figure as an illustration of the behavior of all convex surfaces with respect to all types of light, and conclude that “a convex surface condenses light away from the periphery and towards the sensor’s center.” POR, 24; APPLE-1034 (“...a POSA viewing [FIG. 14B]...would understand that light, *all light*, light from the measurement site is being focused towards the center”).
29. But the incoming collimated light shown in FIG. 14B is not an accurate representation of light that has been reflected from a tissue measurement site. The light rays (1420) shown in FIG. 14B are collimated (i.e., travelling paths parallel to one another), and each light ray’s path is perpendicular to the detecting surface.
30. While each of Inokawa, Aizawa, and Mendelson-1988 are directed to a reflectance-type pulse sensor that detects light that has been backscattered from the

measurement site, the scenario depicted in FIG. 14B shows a transmittance-type configuration where collimated or nearly-collimated light is “attenuated by body tissue,” not backscattered by it. APPLE-1001, 33:65-67. Indeed, FIG. 14I of the ’708 Patent puts FIG. 14B in proper context, showing how light from the emitters is transmitted through the entire finger/tissue before being received by the detectors on the other side:

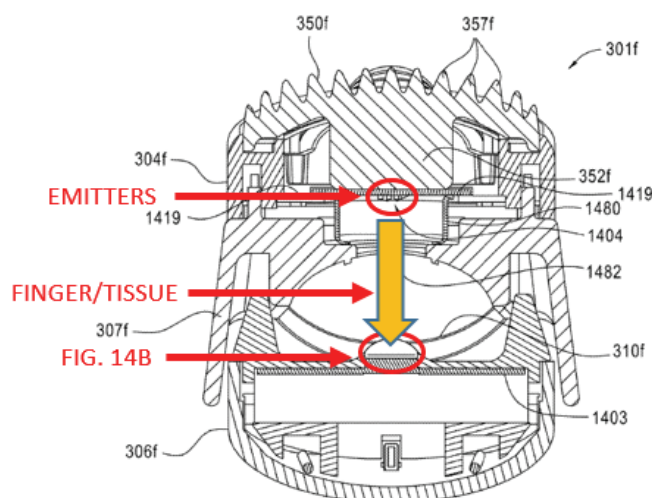
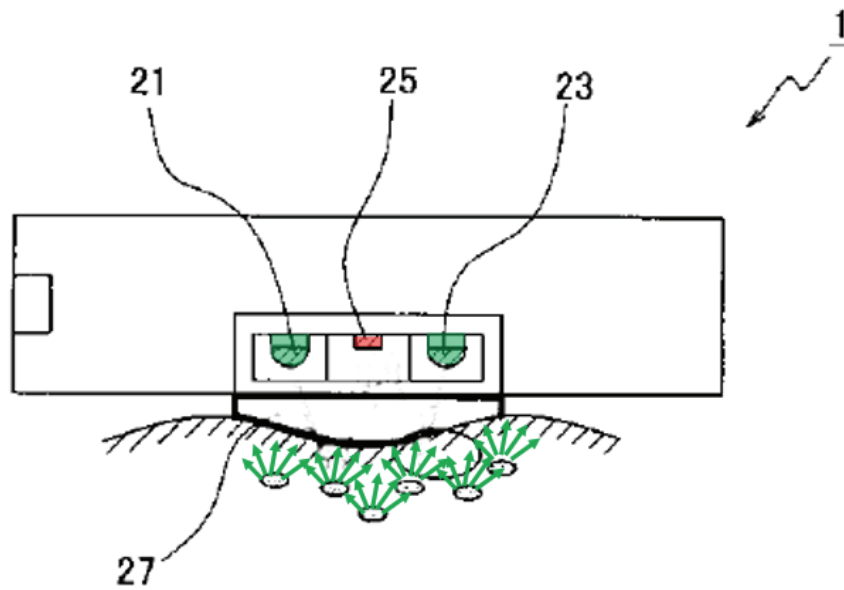


FIG. 14I

31. By contrast, the detector(s) of reflectance type pulse detectors detect light that has been “partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector.” APPLE-1051, 86. For example, a POSITA would have understood from Aizawa’s FIG. 1(a) that light that backscatters from the measurement site after diffusing through tissue reaches the circular active detection area provided by Aizawa’s detectors from various random directions and angles, as opposed to all light entering from the same direction and at

the same angle as shown above in FIG. 14B. APPLE-1051, 52, 86, 90; APPLE-1046, 803-805; *see also* APPLE-1012, FIG. 7. Even for the collimated light shown in FIG. 14B, the focusing of light at the center only occurs if the light beam also happens to be perfectly aligned with the axis of symmetry of the lens. If for example, collimated light were to enter the FIG. 14B lens at any other angle, the light would focus at a different location in the focal plane. Further, if the light were not collimated, so that rays enter the lens with a very wide range of incident angles, there would be no focus at all, and many rays will be deflected away from the center. Moreover, since “the center” takes up a very small portion of the total area under the lens, the majority of rays associated with diffuse light entering the lens would arrive at locations away from the center.

32. The light rays from a diffuse light source, such as the LED-illuminated tissue near a pulse wave sensor or a pulse oximeter, include a very wide range of angles and directions, and cannot be focused to a single point/area with optical elements such as lenses and more general convex surfaces. The example figure below illustrates light rays backscattered by tissue toward a convex lens; as consequence of this backscattering, a POSITA would have understood that the backscattered light will encounter the interface provided by the convex board/lens at all locations from a wide range of angles. This pattern of incoming light cannot be focused by a convex lens towards any single location.



APPLE-1052, 141 (annotated)

33. To the extent Masimo contends that only *some* light is directed “towards the center” and away from Aizawa’s detectors in a way that discourages combination, such arguments also fail. Indeed, far from *focusing* light to a single central point, a POSITA would have understood that Ohsaki’s cover provides a slight refracting effect, such that light rays that may have missed the active detection area are instead directed toward that area as they pass through the interface provided by the lens.

APPLE-1051, 52; APPLE-1007, [0015]; APPLE-1052, 87-92, 135-141; APPLE-1034, 60:7-61:6, 70:8-18.

34. Patent Owner and Dr. Madisetti’s reliance on drawings provided in paragraphs 119-120 of my Original Declaration filed in IPR2020-01520 for justification of their understanding of Inokawa’s lens is similarly misplaced. POR, 15-17; APPLE-1041, 41:7-22, 60:7-61:6. Far from demonstrating the false notion that a convex lens directs all light to the center, these drawings I previously provided are merely

simplified diagrams included to illustrate, as per dependent claim 12, one example scenario (based on just one ray and one corpuscle) where a light permeable cover can “reduce a mean path length of light traveling to the at least four detectors.” Ex. 2020, ¶¶119-120. As previously illustrated, there are many other rays that would intersect the interface between the tissue and the lens at different locations and with different angles of incidence, and the effect of the lens on this variety of rays is not nearly as simple as the statements provided by Dr. Madisetti. There is simply no possibility of any lens focusing all incoming rays from a diffuse light source toward a central location.

B. It would have been obvious to modify Aizawa in view of Ohsaki to include a convex protrusion

35. As explained in my Original Declaration, “Ohsaki teaches that adding a convex surface...can help prevent the device from slipping on the tissue of the wearer compared to using a flat cover without such protrusion” and that “a POSITA seeking to achieve improved adhesion between the detector and the skin, as expressly recognized in Aizawa, would have been motivated and readily able to modify Aizawa’s acrylic plate to have a convex shape as in Ohsaki.” APPLE-1003, ¶¶125-126 (citing to APPLE-1014, [0025]; APPLE-1006, [0026], [0030]).

36. Patent Owner, rather than attempting to directly rebut this rationale, focuses on arguments that are factually flawed and legally irrelevant. Specifically, Patent Owner contends that Ohsaki’s “convex surface must have *longitudinal directionality*,” and that “Ohsaki indicates that its convex surface *only prevents*

slipping on the backhand side (i.e., watch-side) of the user’s wrist.” POR, 37.

Patent Owner further asserts that the shape of Ohsaki’s board must be limited to a long, narrow rectangular shape while ignoring that the specification includes no specific limitation on the shape of the board.

37. Notably absent from the POR is how Ohsaki *actually* describes the benefits associated with its convex surface. For example, Ohsaki contrasts a “convex detecting surface” from a “flat detecting surface,” and explains that “if the translucent board 8 has a flat surface, the detected pulse wave is adversely affected by the movement of the user’s wrist,” but that if “the translucent board 8 has a convex surface...variation of the amount of the reflected light...that reaches the light receiving element 7 is suppressed.” APPLE-1014, ¶[0025]. But a POSITA would have understood from such teachings of Ohsaki that the advantages of a light permeable protruding convex cover could apply regardless of any alleged longitudinal directionality of Ohsaki’s cover and regardless of where on the body such a convex cover was placed. *See* APPLE-1014, ¶¶[0015], [0017], [0025], FIGS. 1, 2, 4A, 4B. This is because Ohsaki was relied upon not for its exact cover configuration but rather for the rather obvious concept that a convex surface protruding into a user’s skin will prevent slippage, regardless of any directionality that may or may not exist with respect to such convex surface and regardless of where on the human body it is located. *See* Ex. 2012, 91, 87; APPLE-1014, ¶¶[0015], [0017], [0025], FIGS. 1, 2, 4A, 4B. In fact, Ohsaki says nothing about the

exact dimensions or even anything specific about the required shape of the board, except that it provides a convex protrusion. A POSITA would seek to combine the board of Ohsaki with Aizawa by making reasonable modifications as needed to ensure that the board of Ohsaki was compatible with the other features present in Aizawa. A POSITA would find it obvious to consider selecting a shape for the board that is consistent with the shape of the system presented in Aizawa, and would expect that the benefits associated with the convex board of Ohsaki would be present in the combination. And adding a convex surface to Aizawa's flat plate will serve to *improve* its tendency to not slip off, not take away from it, since it is well understood that physically extending into the tissue and displacing the tissue with a protrusion provides an additional adhesive effect. Aizawa provides a plate that improves adhesion with the surface. Ohsaki further teaches that the convex protrusion provides "intimate contact" with the tissue, which helps prevent the detecting element from slipping off. These benefits are clearly related and complimentary, and a POSITA would appreciate that modifying the plate of Aizawa to include a convex protrusion as in Ohsaki would provide improved performance, and that these benefits can be obtained by making obvious modifications to the board in Ohsaki to accommodate the shape of Aizawa.

38. Indeed, Ohsaki's specification and claim language reinforce that Ohsaki's description would not have been understood as limited to one side of the wrist. For example, Ohsaki explains that "the detecting element 2...may be worn on the back

side of the user's forearm” as one form of modification. *See* APPLE-1014, [0030], [0028] (providing a section titled “[m]odifications”). The gap between the ulna and radius bones at the forearm is even greater than the gap between bones at the wrist, which is already wide enough to easily accommodate a range of sensor sizes and shapes, including circular shapes. In addition, Ohsaki’s claim 1 states that “the detecting element is constructed to be worn on a back side of a user’s wrist *or a user’s forearm.*” *See also* APPLE-1014, claims 1-2. As another example, Ohsaki’s independent claim 5 and dependent claim 6 state that “the detecting element is constructed to be worn on a user’s wrist or a user’s forearm,” *without even mentioning a backside* of the wrist or forearm. *See also* APPLE-1014, Claims 6-8. A POSITA would have understood that Ohsaki’s benefits provide improvements when the sensor is placed on either side of the user’s wrist or forearm. APPLE-1014, [0025], FIGS. 4A, 4B. And while Masimo appears to contend that Ohsaki teaches that a convex cover at the front (palm) side of the wrist somehow *increases* the tendency to slip, this is an argument that is nowhere supported by Ohsaki. For instance, paragraph 23 and FIGS. 3A-3B of Ohsaki that Masimo points to as allegedly providing support for this incorrect argument mentions nothing about the flat/convex nature of the cover and is instead merely demonstrating that pulse detection is generally less reliable when the user is in motion (and thus would benefit from changes such as adding a convex cover). APPLE-1014, [0024], FIGS. 4A, 4B

39. POR presents several arguments with respect to Ground 1 that are premised on

Ohsaki *requiring* the detecting element to be worn on a back side of a user's wrist or a user's forearm. Because Ohsaki requires no such location for the translucent board 8, these arguments fail.

III. Ground 2 Establishes Obviousness

40. As I further clarify below in response to Patent Owner's arguments, claims 1-9, 11-15, and 19-26 are rendered obvious by the combination of Mendelson-1988 and Inokawa (Ground 2A).

A. Inokawa's lens similarly enhances the light-gathering ability of Mendelson-1988

41. Similar to their rebuttal of the Aizawa-based grounds, Patent Owner contends that (1) "Inokawa's convex lens focused light on a *centrally located* detector" and (2) as a result, incorporating such a lens to Mendelson-1988 would cause the "lens to direct light *away* from the detectors" based on Mendelson-1988's use of centrally-located LEDs. POR, 40-44. For reasons discussed at length above, basic optical principles and a proper understanding of reflectance-type sensors as in Aizawa, Inokawa, and Mendelson-1988 would have led a POSITA to understand that adding an Inokawa-like lens to Mendelson-1988 would result in additional benefits such as enhanced light-gathering ability and improved signal-to-noise ratio. Again, as noted above, Patent Owner's fundamentally flawed characterization of the lens of Inokawa as "focusing [light] on a single central detector" runs contrary to basic principles of optics and how lenses work.

B. Mendelson-1988 in view of Inokawa includes the claimed cover

42. As I previously explained, the Mendelson-1988-Inokawa combination provides protruded epoxy cover that acts as a lens and also covers the detectors. APPLE-1003, ¶¶172-181. Patent Owner argues, however, that “the ’708 Patent distinguishes a resin on a surface from a cover” and, as a result, the modified Mendelson-1988 device lacks a cover. POR, 45-46. Patent Owner further argues that the convex cover in the contemplated combination is somehow not a cover because “it is part of an undifferentiated mass of material.” *Id.*

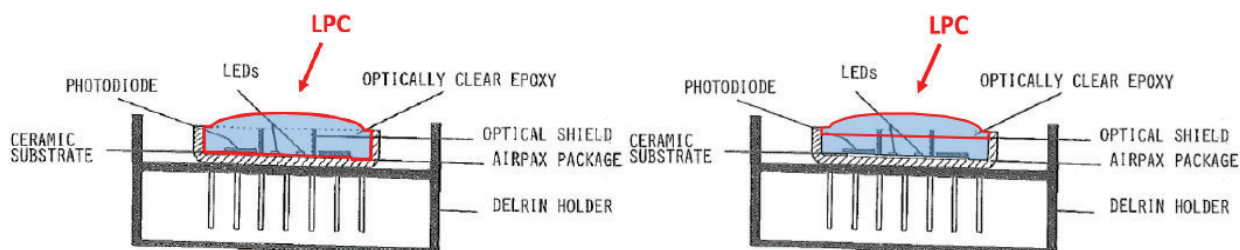
43. A POSITA would understand the plain meaning of cover to be merely “something that protects, shelters, or guards.” APPLE-1050. Both instances of the “light permeable cover” as I previously identified are clearly covers that serve to protect. There is nothing in the specification of the ’295 patent itself that suggests that some special meaning is attributed to the term “cover” as used in the patent.

44. Patent Owner mischaracterizes my deposition testimony to make it sound like I agreed that “sealing resin” is somehow different from a cover. POR, 45-46 (citing to Ex. 2009, 395:22-396:17). My actual testimony, if one reads it fully, clearly shows that no such statement was made. *See* Ex. 2009, 396:9-17 (“Q. So [using a sealing resin] would be one way to protect the components without using a cover, correct? A. There are many ways to protect the elements other than using a cover. The purpose of the cover in this combination is also to improve adhesion and to improve light gathering for the operation of the system.”). Rather, I was merely

clarifying that using a sealing resin is “a pretty common way to protect electronic components.” *Id.*, 395:22-396:8.

45. Moreover, while Patent Owner points to a cherry-picked passage from the '708 Patent to suggest that it distinguishes “cover” from “resin epoxies,” POR, 45-46 (citing APPLE-1001, 36:41-45 (“[The cover] can protect...*more effectively* than currently-available *resin epoxies*.”)), Patent Owner failed to reproduce the rest of the sentence, which reads: “...more effectively than currently-available resin epoxies, *which are sometimes applied to solder joints between conductors and detectors.*” APPLE-1001, 36:37-46. That is, the epoxy resin to which the '708 Patent compares its cover is not the epoxy cover as contemplated in the Mendelson-1988 combination but rather epoxy that is applied to solder joints.

46. As for Patent Owner’s argument that the alternative mapping of the cover shown below right is improper because the identified cover (“LPC”) is somehow “part of an *undifferentiated* mass of material,” the plain meaning of “cover” does not require that the cover be a distinct structure that is completely separated and distinct from surrounding structures. *See* APPLE-1050. Nor does Patent Owner expressly argue for such a construction of “cover.”



POR, 47

47. Under plain meaning, both LPCs as identified above are covers that protect the underlying components. Moreover, to the extent the claimed “cover” must be “distinct” from all other components, I previously explained how a POSITA, looking at conventional epoxy processing techniques such as those found in Nishikawa, would have added an additional epoxy lens layer separately on top of the epoxy encapsulation layer underneath, thereby providing a separate and differentiated mass of material to serve as the cover. APPLE-1003, ¶181 (citing to APPLE-1023, [0034]-[0038], FIGS. 5-6).

**C. Mendelson-1988 in view of Inokawa renders obvious a
“cylindrical housing”**

48. Regarding this feature, I previously explained that there was nothing new or inventive about changing a rectangular housing for a circular one and that a POSITA, among other things because microelectronic packaging as used in Mendelson-1988 comes in various shapes and sizes. APPLE-1003, ¶¶184-186. Patent Owner rebuts this simple change in design by arguing that “[a] POSITA would have no particular motivation to change the shape unless a POSITA perceived some benefit in doing so.” POR, 77-79. But there is nothing in the ’708 Patent or in the POR that explains how the particular housing shape solves some problem or presents some unexpected result. Rather, a POSITA would have simply recognized that housing shape is a non-inventive feature and that it would have been quite routine to use a differently shaped housing. *See* APPLE-1003, ¶¶184-186. Indeed, given that many other references, such as Mendelson-799 (APPLE-1025), explicitly show the use of circular

walls/housings, a POSITA would have found it to be simply a matter of design choice to use a differently shaped walls/housings.

D. Nishikawa is a supporting reference

49. Despite Patent Owner's assertions, I consistently referred to Nishikawa in my Original Declaration merely as an example among various prior art references of the period that "demonstrate exactly how [a convex] lens shape may be incorporated into a molded cover." APPLE-1003, ¶¶89, 178-179. That is, Nishikawa merely provides further support for my actual combination (*i.e.*, Mendelson-1988 in view of Inokawa) by demonstrating how the lens of Inokawa may be incorporated in a manufacturing context. *Id.*

IV. CONCLUSION

50. I reserve the right to supplement my opinions to address any information obtained, or positions taken, based on any new information introduced throughout this proceeding.

51. I declare under penalty of perjury that the foregoing is true and accurate to the best of my ability.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.

Petitioner,

v.

MASIMO CORPORATION,

Patent Owner.

Case IPR2021-00193
U.S. Patent 10,299,708

DECLARATION OF VIJAY K. MADISETTI, PH.D.

| |
|--|
| Masimo Ex. 2004 Apple v. Masimo IPR2021-00193 |
|--|

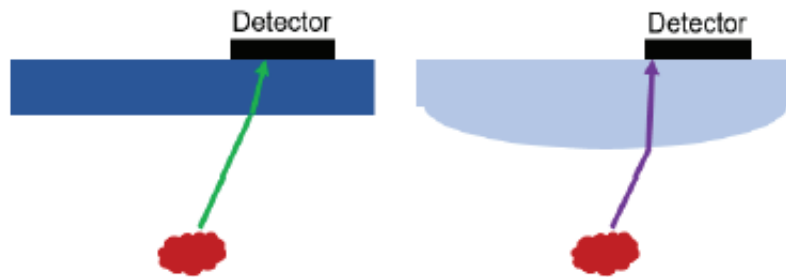
B. Ground 1A Does Not Establish Obviousness Because A POSITA Would Not Have Been Motivated To Combine Inokawa’s Convex Lens With Aizawa’s Sensor

1. Dr. Kenny and Petitioner Admit That Inokawa’s Convex Lens Directs Light To The Center Of The Sensor

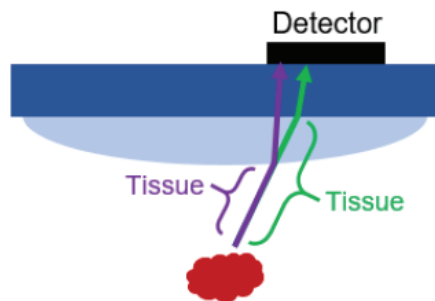
50. Both Dr. Kenny and Petitioner agree that Inokawa’s convex lens condenses light towards a centrally located detector—not periphery-located detectors like those used in Aizawa, as demonstrated by their submissions in an IPR (IPR2020-01520 (Ex. 2019; Ex. 2020)) of related patent U.S. Pat. No. 10,258,265 (Ex. 2025). U.S. Pat. No. 10,258,265 and the ’708 Patent share a common specification. U.S. Pat. No. 10,258,265 is at least a continuation of U.S. Patent App. No. 14/981290. The ’708 Patent is at least a continuation of U.S. Patent App. No. 16/212537, which is at least a continuation of U.S. Patent App. No. 14/981290.

51. Petitioner included the illustrations below in its Petition in IPR2020-01520 when discussing claim 12 of U.S. Pat. No. 10,258,265. Ex. 2019 at 45. Petitioner explained that “the lens/protrusion of Inokawa, which is used to modify Aizawa ... serves a condensing function and thus, as with any other lens, refracts light passing through it.” Ex. 2019 at 44. Petitioner explained the drawing below as comparing “the length of non-refracted light (i.e., without a lens, left) bouncing off an artery with that of refracted light (i.e., with a lens, right).” Ex. 2019 at 44-45. Refraction is a phenomenon related to the velocity of light in different

materials because the velocity of light depends on the material through which it is traveling. Thus, the change in velocity as light moves from one material to another material may cause the light to deviate from its original direction, which is called “refraction.” I note that the illustration below shows refraction for both the flat and convex surfaces because in both instances the illustrated light ray changes direction. Moreover, I note that, as illustrated by Petitioner, the change of direction for the light ray hitting the convex surface is relatively more towards the center of the cover than for the flat cover. Petitioner states that the result of the greater refraction of light with the convex cover with a protruding surface is that “the mean path length of light traveling to the at least four detectors is reduced—that is, the purple line is shorter than the redline [sic green line].” Ex. 2019 at 45. Petitioner also includes a drawing superimposing the two drawings below to “clearly show[] the shortened path traveled by refracted light in the presence of a protrusion/lens, both within the tissue as well as for total path length.” Ex. 2019 at 45.



From A Related IPR (Ex. 2019):
 Petitioner's illustration of redirection of the mean path length
 of light traveling to the detectors when passing
 through a flat (left) and convex (right) cover (Ex. 2019 at 45)



From A Related IPR (Ex. 2019):
 Petitioner's illustration superimposing the above refractions
 when illustrating how a convex surface a protruding surface changes the
 mean path length of incoming light (Ex. 2019 at 45, 91)

52. Dr. Kenny also included and explained the two figures above in his declaration in IPR2020-01520 (Ex. 2020) as a way to illustrate the mean path length of light. Ex. 2020 at 69-70. Dr. Kenny explained that, when using a protruding surface such as Inokawa's convex lens, "the incoming light is 'condensed' toward the center." Ex. 2020 at 69-70. Dr. Kenny goes on to explain: "Laying these two drawings on top of each other...the shortened path length within

the tissue for the purple (refracted) line can be clearly seen compared to the path length within the tissue of the green (non-refracted) line.” Ex. 2020 at 70-71.

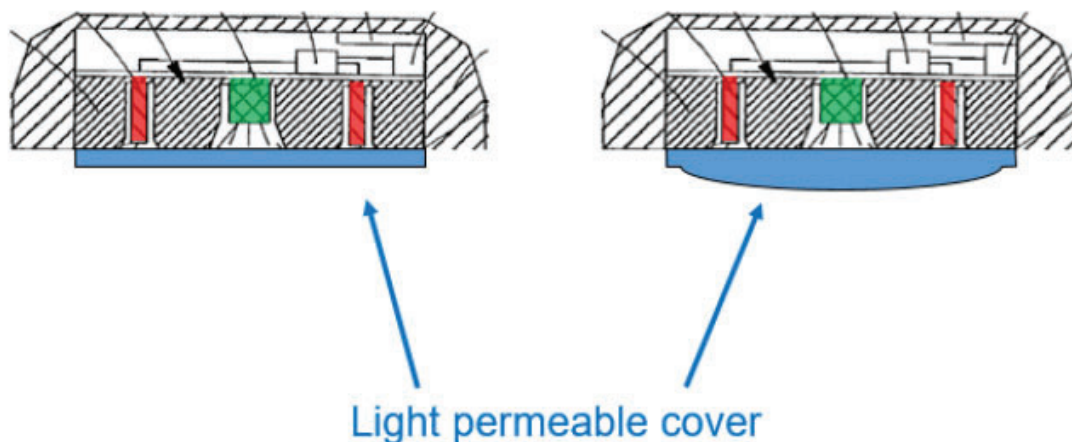
53. The understanding expressed by Petitioner and Dr. Kenny about condensing light is consistent with Inokawa’s disclosure, which uses a convex surface as a way to increase the light gathering capability for a centrally located detector. Ex. 1008 ¶[0058], Fig. 2. As shown in Figure 2 (below), Inokawa illustrates how a protruding surface placed between the sensor and the skin condenses incoming light towards the central detector 25. Ex. 1008 ¶[0058], Fig. 2. This is helpful for Inokawa’s particular sensor configuration because the emitters are located on the edges of the sensor while the detector is located in the center of the sensor. Thus, for Inokawa’s particular linear arrangement of emitter-sensor-emitter, the protruding shape is reported to increase the light gathering capabilities of the centrally located detector when collecting the light emitted by the periphery-located LEDs and reflected by the measurement site. Ex. 1008 ¶[0058], Fig. 2. Inokawa illustrates this by using arrows that illustrate the general path of light from emitters, to the measurement site, and then back towards the central detector.

the proposed combination, redirects incoming light that would otherwise hit a more peripheral location (i.e., than if no protruding surface was present) to a more central location as a result of passing through the protruding surface. Ex. 1001 Fig. 14B.

57. Thus, as discussed, Petitioner, Dr. Kenny, and the '708 Patent all support that a POSITA would have understood that the protruding surface illustrated by Inokawa would direct incoming light towards the center of the sensor. I also agree that a POSITA reading Inokawa would have understood that the protruding surface illustrated by Inokawa would direct incoming light towards the center of the sensor.

2. A POSITA Would Not Have Been Motivated To Direct Light Away From Aizawa's Detectors And Would Have No Reasonable Expectation Of Success When Doing So

58. Although Petitioner and Dr. Kenny both agree that a POSITA would have understood that a protruding surface would converge incoming light toward the center, I understand that Petitioner asserts that a POSITA would place Inokawa's convex lens on the sensor of Aizawa, which has the opposite configuration of components as compared to Inokawa, with peripheral detectors and a central emitter. Petitioner illustrates the result of this change in Aizawa as a device with the emitter (green) in the center and the detectors (red) on the periphery.



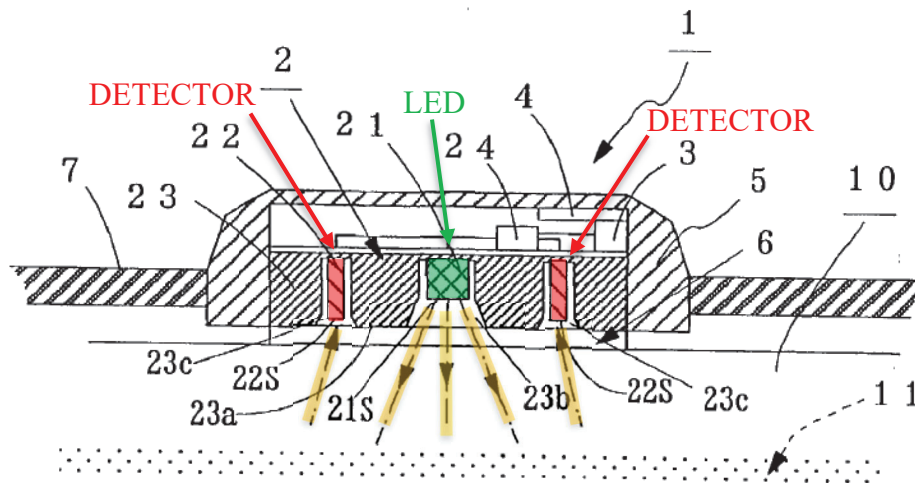
Petitioner's and Dr. Kenny's illustrations (Pet. 24; Ex. 1003 ¶87)
 Aizawa's flat surface (left) versus Ground 1A's Proposed Combination (right)
 The detectors are red and the emitter is green.

59. Dr. Kenny illustrates this same combination in his declaration. Ex. 1003 ¶87. Dr. Kenny states that “by positioning a lens above the optical components of Aizawa, as shown below, the modified cover will allow more light to be gathered and refracted toward the light receiving cavities of Aizawa, thereby further increasing the light-gathering ability of Aizawa beyond what is achieved through the tapered cavities.” Ex. 1003 ¶87. As shown in Inokawa, as well as Dr. Kenny's other figures in his declaration and the '708 Patent, however, a POSITA would not have believed that the illustrated protruding surface would have allowed “more light to be gathered and refracted toward” Aizawa's peripheral detectors. Instead, as discussed above, a POSITA reading Inokawa would have expected more light would be gathered and refracted towards the center of the sensor, which is where Aizawa positions its single emitter.

60. Like Dr. Kenny, Petitioner asserts that a POSITA would have been motivated to “further Aizawa’s objective of enhancing its light-collection efficiency.” Pet. 23-24. But, again, a POSITA would not have expected Inokawa’s protruding surface to accomplish this goal because, as discussed, a POSITA would have understood that a protruding surface directs light away from the periphery-located detectors. Ex. 1008 ¶[0058], Fig. 2. Thus, in view of Inokawa’s teachings of increased light gathering to its central detector, a POSITA would have believed that a protruding surface would have undesirably decreased light-collection efficiency at Aizawa’s peripheral detectors and reduced the measured optical signal. Ex. 1008 ¶[0058], Fig. 2.

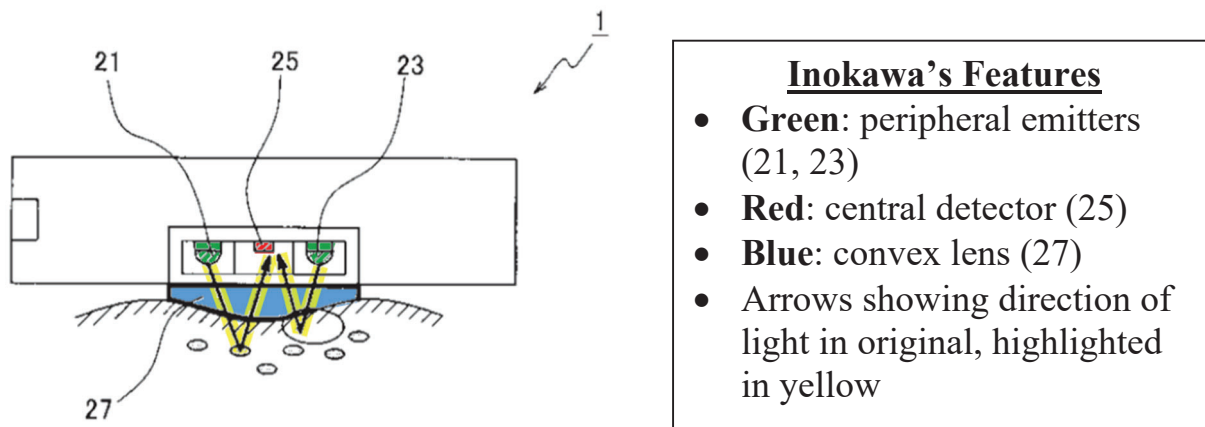
61. As illustrated in Aizawa, light is emitted from a central emitter (e.g., a light emitting diode or “LED”) and reaches detectors (e.g., photodetectors) that are disposed around the emitter. Ex. 1006 ¶[0009]. The light emitted from the center-located emitter reflects from the artery of the wrist of the user and travels to the periphery located detectors. Ex. 1006 ¶¶[0009], [0027], [0036]. Thus, as illustrated in Aizawa Figure 1B, the light reaching Aizawa’s detectors must travel in the opposite direction compared to the light in Inokawa. Ex. 1006 Fig. 1B. Aizawa states that its detectors “are disposed around the light emitting diode 21 on a circle concentric to the light emitting diode 21 in this embodiment.” Ex. 1006 ¶[0027]. Aizawa contrasts its circular arrangement of detectors around an emitter

with the type of linear arrangement illustrated in Inokawa, explaining the photodetectors “should not be disposed linearly.” Ex. 1006 ¶[0027]; *see also* ¶¶[0009], [0036]. Aizawa illustrates the light path as leaving a single centrally located emitter, passing through the body, and reflecting back to periphery-located detectors:



Aizawa Fig. 1B (cross-sectional view, color added)

62. As shown below, Inokawa illustrates the opposite emitter/detector arrangement and the opposite required light path for detection: light leaves periphery-located emitters, passes through the body, reflects back, and is focused on a single centrally located detector. Ex. 1008 ¶[0058], Fig. 2.

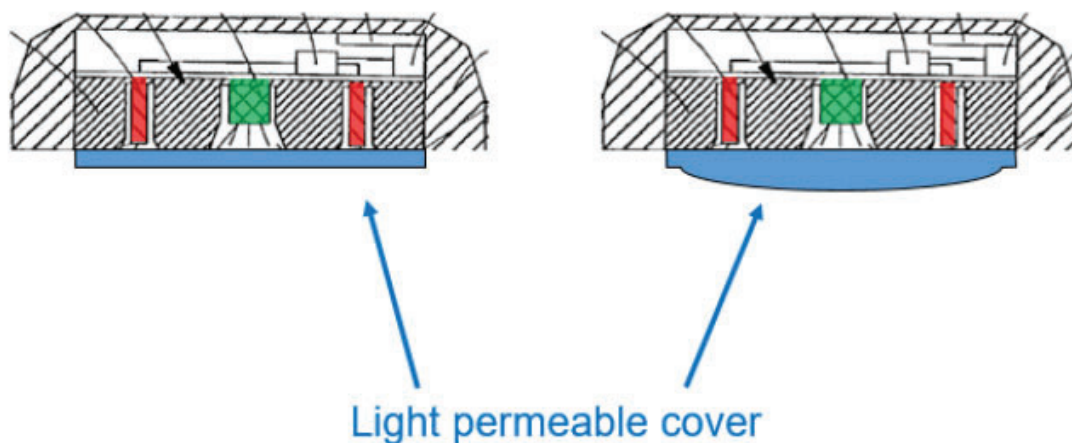


Inokawa Fig. 2 (color added)

63. In my opinion, a POSITA would have linked the benefit of increased light gathering described in Inokawa to the arrangement of peripheral emitters and center-located detector, and thus would have believed that the benefit of increased light gathering resulting from Inokawa's protruding surface made sense in view of Inokawa's configuration using a centrally located detector. Ex. 1008 ¶[0058], Fig. 2. In contrast, a POSITA would have understood that Inokawa's protruding surface would not be suitable for achieving a goal of improved light gathering in Aizawa's sensor, because Aizawa uses a circular arrangement of peripheral detectors arranged around a central emitter and contrasts its approach to a linear detector/emitter arrangement. Ex. 1006 ¶¶[0009], [0027], [0036], Fig. 1B; *see also* Figs. 1A, 2, 4, 5.

64. As shown in the structure that Dr. Kenny and Petitioner assert would have resulted from the proposed combination of Inokawa and Aizawa (reproduced

below), the result of the proposed combination places the emitter at the very center of the protruding surface, which is the position at which the returning light would be concentrated.

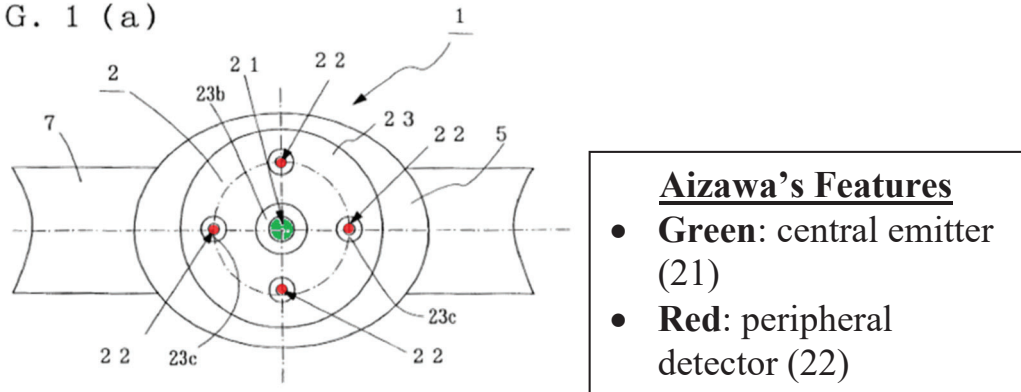


Petitioner's and Dr. Kenny's illustrations (Pet. 24; Ex. 1003 ¶87)
Aizawa's flat surface (left) versus Ground 1A's Proposed Combination (right)

65. In my opinion, a POSITA would have found this combination of a protruding surface with Aizawa's sensor particularly problematic because—consistent with Aizawa—the combination includes small detectors with small openings surrounded by a large amount of opaque material. Pet. 24; Ex. 1003 ¶87; Ex. 1006 Fig. 1B; *see also* Figs. 1A, 2, 4, 5. Aizawa's top-down view shown in Figure 1A confirms the detectors' small size. Ex. 1006 Fig. 1A; *see also* Figs. 2, 4. Aizawa Figure 1A is reproduced below with the detectors highlighted in red and the emitters highlighted in green. Aizawa explains that the openings of the detector cavities (23c in the figure below) are larger than the size of the

photodetector itself, and intended to “expand...the light receiving areas of the photodetectors... [and] are tapered such that their widths increase toward the contact face.” Ex. 1006 ¶[0024].

FIG. 1 (a)



3. Dr. Kenny's Testimony Further Undermines Obviousness

66. Dr. Kenny's declaration in IPR2020-01520 includes figures that he describes as illustrating the phenomenon of how “the incoming light is ‘condensed’ toward the center,” after interacting with a protruding surface. Ex. 2020 at 69-70. The term “condensing” in the context of light passing through a surface describes the general understanding of a POSITA that light is directed towards a more central location when passing through a protruding surface, and thus results in a relative increase of light at the center and decrease of light at the peripheral edge of underlying structure. I further note that the figures at pages 69-70 in Dr. Kenny's declaration in IPR2020-01520 are used with respect to a limitation involving the “mean path length of light traveling to the at least four detectors.” Ex. 2020 at 69-71, 115-117. In particular, the limitation Dr. Kenny analyzed in that declaration is:

73. Dr. Kenny's and Petitioner's asserted level of skill (1) requires no coursework, training or experience in optics or optical physiological monitors; (2) requires no coursework, training or experience in physiology; and (3) focuses on data processing and not sensor design. Training in data processing would not have prepared a POSITA for the type of design process identified by Dr. Kenny as needed to develop a working optical physiological sensor.

74. A POSITA would have understood that Inokawa's convex lens benefits Inokawa's sensor design with its center-located detector. Ex. 1008 ¶58, Fig. 2. In my opinion, a POSITA would have credited the teaching of Inokawa itself, which shows that a protruding surface directs incoming light towards the center. Ex. 1008 ¶58, Fig. 2. In contrast, I do not believe a POSITA would have been motivated to go through Dr. Kenny's extensive trial and error process to try and figure out whether Inokawa's protruding surface would have analogous benefits in a device with peripheral detectors and a central emitter. Instead, a POSITA would have taken Inokawa's teaching at face value, consistent with the general understanding of how light interacts with a protruding surface.

75. Thus, accounting for the possibility that a POSITA with no experience in optical physiological sensor design would nonetheless understand the wide ranging considerations identified by Dr. Kenny at his deposition in related IPRs, it is still my opinion that Inokawa does not establish a valid motivation to combine

Inokawa with Aizawa, much less a reasonable expectation of success. When addressing a reasonable expectation of success, Dr. Kenny focuses his discussion on the manufacturing of a device, and not whether the device would be able to successfully act as a physiological monitor or sensor. See, e.g., Ex. 1003 ¶¶88-89. Whether or not “the shape of the cover can be readily modified” (Ex. 1003 ¶88), Dr. Kenny never explains why a POSITA would have expected Petitioner’s proposed combination to result in a successful optical physiological sensor. The lack of analysis is particularly important because a POSITA would have expected a protruding surface to decrease the optical signal at the peripheral detectors. The possibility that a POSITA could manufacture a device is not evidence a POSITA would have reasonably expected the resulting device to successfully work as an optical physiological measurement device. Decreasing the amount of light reaching the detectors will decrease the signal, increase the relative amount of noise, and could thus result in a signal unusable for actually monitoring a physiological parameter.

4. Petitioner’s Obviousness Challenge Also Relies On References Not Identified As Part Of Ground 1A Without A Motivation To Combine Or Expectation Of Success

76. I further note that the Petition, and Dr. Kenny’s analysis, apparently relies on references that neither the Petitioner nor Dr. Kenny identifies as part of Ground 1A. The Petition states that Ground 1A includes only two references:

1. Ohsaki Does Not Fix The Problems With Ground 1A's Proposed Aizawa-Inokawa Combination

82. Dr. Kenny asserts that Ohsaki would have provided an additional motivation to incorporate Inokawa's convex lens into Aizawa to "help prevent the device from slipping." Ex. 1003 ¶¶125-126. But Ohsaki does not address or correct the problem with the proposed combination, which, as discussed above, is that a POSITA would have believed that a protruding surface, such as the one in Inokawa or Ohsaki, would direct light away from Aizawa's peripheral detectors. In my opinion, the desire to prevent slipping would not have motivated a POSITA to create a device that would have been expected to reduce the signal strength.

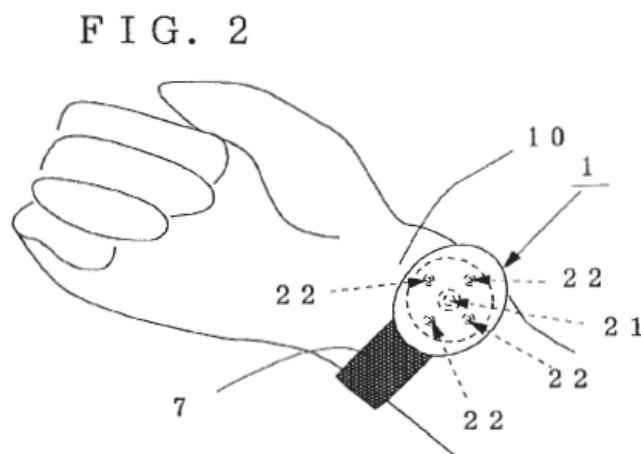
2. A POSITA Would Have Understood That Ohsaki's Board Would Not Prevent Slipping With Aizawa's Device

83. Dr. Kenny also does not establish any benefit to introducing Ohsaki's convex board to Aizawa's device. Dr. Kenny states that "Ohsaki teaches that adding a convex surface to its translucent board 8 (i.e., light permeable cover) can help prevent the device from slipping on the tissue of the wearer compared to using a flat cover without such a protrusion." Ex. 1003 ¶125; *see also* ¶126 ("In other words, a POSITA seeking to achieve improved adhesion between the detector and the skin, as expressly recognized in Aizawa, would have been motivated and readily able to modify Aizawa's acrylic plate to have a convex shape as in Ohsaki."). But Ohsaki's disclosure indicates any benefit to its board is

exceptionally limited. First, Ohsaki indicates that the “detecting element” (2) must have longitudinal directionality, which I understand to mean it must be rectangular in shape. Ex. 1014 ¶[0019]. Ohsaki shows the long side of the rectangle in Ohsaki Figure 2. Ex. 1014 ¶[0019]. This long direction is pointed up and down the user’s arm. Ex. 1014 ¶[0019]. The board (8) spans most of the long direction in Ohsaki’s detecting element. Ex. 1014 Fig. 2. Ohsaki also illustrates the short direction of the detecting element (2) (which is in the “circumferential” direction of the wrist) in Figure 1. Ex. 1014 ¶[0019], Fig. 1. Figure 1 shows that in the short direction, the board is considerably narrower than the detecting element (2). Thus, a POSITA would have understood that Ohsaki’s board is long, narrow, and rectangular. Ohsaki indicates that one must orient the sensor and the accompanying rectangular board with the longitudinal direction of the user’s arm to prevent slipping. Ex. 1014 ¶[0019]. Third, Ohsaki indicates that the protruding surface only prevents slipping on the backhand side (i.e., watch-side) of the user’s wrist. Ex. 1014 ¶[0024]. Ohsaki’s sensor has “a tendency to slip off” if it is on the palm side of the user’s wrist. Ex. 1014 ¶[0023], Figs. 3A-3B. As shown in Ohsaki Figure 3B, a measurement using a sensor with a convex board that is taken from the “front side” (the “palm side”) of the wrist has a similar amount of motion noise as a flat surface used on the backhand side of the wrist (Figure 4B), which Ohsaki

deems is “adversely affected by movement.” See Ex. 1014 ¶[0025] (discussing the flat surface measurements in Figure 4B), Figs. 3A-3B, 4A-4B.

84. Aizawa is different from Ohsaki on each of these issues. First, rather than using a rectangular longitudinal directionality, Aizawa uses a circular arrangement of detectors disposed around a central emitter. Ex. 1006 ¶¶[0009], [0027], [0036]. Aizawa distinguishes its sensor from linear sensors such as Ohsaki’s sensor. Ex. 1006 ¶¶[0009], [0027], [0036]. Second, a POSITA could not place Aizawa’s circular surface with the longitudinal direction of the user’s arm. Ex. 1014 ¶[0019]. This is because its circular shape means that Aizawa’s sensor points in all directions equally. Third, Aizawa’s sensor is positioned on the palm side of the wrist. Ex. 1006 Fig. 2 (below). Aizawa requires this positioning so that the sensor “becomes close to the artery...of the wrist.” Ex. 1006 ¶[0026]; *see also*, *e.g.*, Abstract, ¶¶[0002], [0009], [0027].



Aizawa’s sensor shown on palm side of wrist (Ex. 1006 Fig. 2)

85. Thus, a POSITA would not have believed Ohsaki's longitudinal protruding surface would benefit Aizawa's device. Ohsaki teaches that a protruding surface on the palm side of the wrist would not prevent slipping. Ex. 1014 ¶[0023], Figs. 3A-3B. This is shown in Ohsaki Figures 3B's motion signal, which illustrates that Ohsaki's sensor experiences considerable movement and slipping on the palm side (front side) of the wrist, as compared to Figure 3A's motion signal on the back side of the wrist. Thus, a POSITA would have had no motivation to add such a protruding surface to Aizawa's palm-side sensor. Instead, Aizawa reports that on the palm side of the wrist, a flat surface improves adhesion. Ex. 1006 ¶¶[0013], [0026], [0030], [0034]; *see also* Figs. 3A-3B, ¶[0028] (illustrating Aizawa's output of photodetector). Thus a POSITA would have believed that adding Ohsaki's protruding surface would have disrupted the improved adhesion properties reported for Aizawa's flat plate, in view of Ohsaki's reported slipping and noise for a protruding surface positioned on the palm side (front side) of the wrist. Ex. 1014 ¶¶[0023]-[0024], Figs. 3A-3B. Ohsaki's teachings are also incompatible with Aizawa's sensor positioning and design because—as discussed—Aizawa requires measurements from “the artery of a wrist.” Ex. 1006 ¶¶[0002], [0009], [0026], [0027], [0036]. Wrist arteries are near the surface on the palm side of the wrist. Ex. 2010 at 44 (Plate 429) (showing

radial and ulnar arteries in superficial layer of the anterior (palm side) of wrist), compare at 71 (Plate 456) (showing arteries on palm side of upper limb).

E. The Challenged Dependent Claims Are Nonobvious Over Ground 1B

86. The Petition does not establish that independent claims 1 and 19 are obvious based on the proposed combination of references in Ground 1B. It also does not establish that any of the challenged dependent claims are obvious for the same reasons as for claims 1 and 19.

F. Grounds 1C-1F Fail For The Same Reasons As Ground 1A

87. Grounds 1C-1F address dependent claims only and do not address or fix the deficiencies in the analysis of the independent claims discussed for Ground 1A or 1B above. These claims are thus non-obvious for the same reasons.

VIII. GROUNDS 2A-2C DO NOT ESTABLISH OBVIOUSNESS

A. Introduction To Ground 2A

88. Ground 2A combines two references: Mendelson-1988 (Ex. 1015) and Inokawa (Ex. 1008). Pet. 2. Grounds 2B-2C challenge certain dependent claims, but likewise relies on the combination of Mendelson-1988 and Inokawa in combination with additional references. Pet. 2

B. Ground 2A Does Not Establish Obviousness

1. Ground 2A Does Not Demonstrate A Motivation To Combine Mendelson-1988 And Inokawa, And Does Not Establish A Reasonable Expectation Of Success

94. The proposed combination of Mendelson-1988 and Inokawa suffers from the same problems as the proposed combination of Aizawa and Inokawa. In the proposed Mendelson-1988-Inokawa combination, as in the proposed Aizawa-Inokawa combination, the detectors are on the periphery of the device. Ex. 1015 at 2, Figs. 2A-2B. As explained above, Inokawa's convex lens focuses light on a centrally located detector. *See* ¶¶42-63 and 66-75 of this declaration, above; *see also* Ex. 2020 at 115-117 (Dr. Kenny explaining that light passing through a convex surface is condensed towards the center relative to a flat surface). A POSITA would not have been motivated to incorporate a protruding surface to direct light away from the detectors for the same reasons discussed above. *See* ¶¶42-63 and 66-75 of this declaration, above.

95. As shown in Dr. Kenny's illustration below, the proposed combination of Mendelson-1988 and Inokawa positions detectors (Mendelson-1988's photodiodes) on the periphery of the sensor:

4/22/2021

Apple, Inc. v. Masimo Corp.

Thomas Kenny Jr., Ph.D.

Page 1

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

| | | |
|---------------------|---|--------------------------|
| APPLE INC., |) | |
| |) | IPR NO. 2020-1520 |
| Petitioner, |) | US PATENT NO: 10,258,265 |
| |) | |
| -against- |) | IPR NO. 2020-1537 |
| |) | US PATENT NO: 10,588,553 |
| MASIMO CORPORATION, |) | |
| |) | IPR NO. 2020-1539 |
| Patent Owner. |) | US PATENT NO: 10,588,554 |
| |) | |

VIDEO-RECORDED DEPOSITION OF
THOMAS WILLIAM KENNY, JR. PH.D.

VOLUME 1

Zoom Recorded Videoconference

04/22/2021

9:02 a.m. (Pacific Daylight Time)

REPORTED BY: AMANDA GORRONO, CLR
CLR NO. 052005-01

DIGITAL EVIDENCE GROUP
1730 M Street, NW, Suite 812
Washington, D.C. 20036
(202) 232-0646

Masimo Ex. 2006
Apple v. Masimo, IPR2021-00193

4/22/2021

Apple, Inc. v. Masimo Corp.

Thomas Kenny Jr., Ph.D.

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1 reach a conclusion, if there was a solid improvement
2 provided by your design change.

3 Q. And what, what are the challenges
4 with doing a ray trace analysis, looking at the
5 possible pathways of light through the system and
6 trying to assess how much light is able to reach a
7 detector?

8 MR. SMITH: Objection; form.

9 A. So there are many detailed
10 differences between what might be the ideal
11 representation of the system and the actual
12 representation, the behavior of the elements and so
13 on, within specifications.

14 Q. I just want to make sure that, that
15 the transcript was correct here. Did you say "so
16 there are many detail differences between what might
17 be the ideal representation of the system and the
18 actual representation, the behavior of the elements
19 and so on, within specifications."

20 Did I read that correctly?

21 A. Let me cleanup a bit. The drawings
22 such as here on the bottom of page 55 shows, you

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1 know, certain shapes and sizes perhaps to scale with
2 certain levels of accuracy. If I was asked to
3 analyze the optical performance of a system like
4 this, I would need to know precisely the shapes and
5 the tolerances around those shapes, the position of
6 the elements, the detectors, the emitters and so on.
7 And there's tolerances around all of that.

8 And then an analysis can be done. A
9 person of ordinary skill in the art would know how to
10 represent the details and the tolerances within some
11 analytical framework and produce estimates of the
12 relative performance, with and without your
13 improvement.

14 Q. Did you do that analysis in this
15 case?

16 A. No.

17 Q. Can you explain the difference
18 between the analysis you did and the analysis that
19 you just described that a person of ordinary skill in
20 the art would do to sort of examine the differences
21 between the ideal representation of a system and the
22 actual representation or behavior of the system?

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1 case provide refraction and concentration of the
2 incoming light.

3 Q. So is it your testimony that a person
4 of ordinary skill in the art looking at the Inokawa
5 figure following Paragraph 110 would not be able to
6 determine whether it concentrates light to any
7 particular location?

8 MR. SMITH: Objection; form.

9 A. So we've gone around this a bit.
10 The, the way the light is concentrated depends on
11 where it's coming from and in particular
12 orientations, details of shapes, index of refraction.
13 So there's not enough information in this drawing to
14 identify a precise location or any particular
15 precision around the concentration of the light.

16 One of ordinary skill in the art
17 would understand that this general shape of a
18 lens-like feature can provide that benefit.

19 Q. What benefit?

20 A. The benefit of refracting and
21 concentrating the light coming in through the, the
22 lens.

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1 Q. But without more information, a
2 person of ordinary skill in the art would not
3 understand where that light is being concentrated on
4 the -- you know, after, after it enters the lens and
5 exits the lens?

6 MR. LARSON: Let me restate that.

7 Q. Without more information, a person of
8 ordinary skill in the art looking at the Inokawa
9 figure you put after Paragraph 110 would not be able
10 to understand how the light is concentrated after it
11 exits the lens and --

12 A. One of, one of ordinary skill in the
13 art would understand that the lens-like feature can
14 provide that benefit. It would be obvious that one
15 could obtain that benefit. And then the detailed
16 design would, would be carried out to determine the
17 precise location and maximize that benefit. But
18 it's, it's plainly obvious that that benefit is
19 available by combining these features.

20 Q. So in, in the figure from Inokawa
21 that you have following Paragraph 110, if you started
22 with a flat cover and I said let's change that to the

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1 convex shape shown in, shown in the picture of
2 Inokawa that you have following Paragraph 110, would
3 a person of ordinary skill in the art be able to
4 determine how light would be concentrated based on
5 that change and structure?

6 MR. SMITH: Objection; form.

7 A. So the general question of if I take
8 the flat example and modify it with a lens-like
9 convex curvature without specifying the details of
10 any of it, would the person be able to tell me where
11 the concentration exactly would happen? There's --
12 that's an insufficiently specified question.

13 Q. What's insufficiently specified about
14 my question?

15 A. There's a lot of things missing. So
16 the exact dimensions of the structures that you
17 created, the index of refraction of that material
18 relative to the surrounding materials, the location
19 of the light source, in this case being the light
20 that's reflected off of the corpuscles.

21 I can go on. It's a -- the figure is
22 intended as illustration of the concept. The details

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1 of a particular implementation are not represented in
2 this figure.

3 Q. So what concept does the figure
4 represent?

5 A. This figure shows the use of a
6 protruding convex surface to provide improvement in
7 the signal-to-noise ratio through refraction and
8 concentration of the light coming in.

9 Q. But a person of ordinary skill in the
10 art looking at this figure would not understand how
11 changing from a flat surface to a convex shape would
12 impact the concentration of light; is that, is that
13 your testimony?

14 MR. SMITH: Objection; form.

15 A. I think a person of ordinary skill in
16 the art would understand that replacing a flat
17 surface with a convex surface, as illustrated in this
18 figure, has the potential of improving the
19 concentration of the light, subject to, you know,
20 further refinement of the design, which is what a
21 person of ordinary skill in the art would then
22 proceed with.

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1 art, looking at Figure 2 from Inokawa, would believe
2 the lens-like feature provides the benefit of
3 increased light at the center detector, correct?

4 MR. SMITH: Objection; form.

5 Q. I think I just repeated my last
6 question, which --

7 A. I know. Again, I feel like I'm
8 repeating all my answers. It's -- you know, one
9 would understand that this convex lens-like shape
10 increases light-collection efficiency. The shape
11 provides this benefit by refracting and concentrating
12 the light coming in through the acrylic plate after
13 being reflected by the light. Yes, I think that's
14 what I've been saying.

15 Q. Right. The part I'm focusing on that
16 I think you agree with but you don't specify in your
17 answer is that it provides this benefit by
18 concentrating light towards the detector in the
19 center, correct?

20 MR. SMITH: Objection; form.

21 A. Yeah. Inokawa teaches that the lens
22 makes it possible to increase the light-gathering

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1 ability and particularly for -- with respect to his
2 own illustration, yes.

3 Q. Okay. And so a person of ordinary
4 skill in the art, looking at Figure 2 of Inokawa,
5 would believe that the lens-like feature concentrates
6 light toward, toward the center detector, correct?

7 MR. SMITH: Objection; form.

8 A. So I want to be careful not to make a
9 statement that's too general here, and that's, that's
10 why I'm hesitating. They have other examples.

11 For example, Aizawa, where the
12 detectors are not in the center, they are scattered
13 around the perimeter. I'd say for a case of this
14 particular alignment in Inokawa where the center axis
15 of the lens and the detector are aligned, that one of
16 ordinary skill in the art would understand that that
17 arrangement provides, in that particular case, the
18 described feature of increased -- let me just find
19 exactly the right point in the invention here -- you
20 know, that arrangement increases the light-gathering
21 ability.

22 So, you know, this Inokawa is an

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1 Q. Well, we can get there in a moment.

2 But let me just ask you about Figure 2 in Inokawa.

3 And I'm not proposing that you change the lens or any
4 of the structure in any way, other than to put the
5 LED in the middle and detectors on the outside.

6 And my question to you is: Would a
7 person of ordinary skill in the art have understood
8 that even in that configuration the lens would still
9 concentrate light towards the center, correct?

10 MR. SMITH: Objection; form.

11 A. So I think one of ordinary skill in
12 the art would understand that a lens, in general, can
13 provide concentration of light. The locations and
14 directions of that concentration depend on the
15 details of the design of the lens, the location of
16 the sources, and the location at which you're
17 interested in the presence or absence of
18 concentration.

19 I think one of ordinary skill in the
20 art would understand that in Inokawa the objective is
21 to concentrate light at the detector, which is in the
22 center axis of the drawing and that the lens is

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1 capable of providing that benefit.

2 If we're going to move the lenses and
3 the LEDs and detectors around and ask different
4 questions, it's -- it isn't so obvious that Inokawa
5 is specifically considering those scenarios. It's a
6 little more hypothetical.

7 Q. I don't think that answers my
8 question, to be quite honest with you. My question
9 is Figure 2 in Inokawa, you testified that a person
10 of ordinary skill in the art would look at that and
11 understand that the lens combines the benefit of
12 directing light towards the center detector. And I'm
13 asking if, if the only thing you change in Figure 2
14 of Inokawa was to put the LED in the center and the
15 detectors on the outside, wouldn't the lens still
16 concentrate light towards the center?

17 MR. SMITH: Objection; form.

18 A. So in that arrangement, the lens does
19 many things to different rays of light coming in from
20 different directions, different reflection spots,
21 different corpuscles for light along the axis coming
22 into the lens. As I explained, the lens, that

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1 particular shape, one would understand that that lens
2 would provide concentration towards the center in
3 addition to effects on light rays elsewhere in the
4 system that might also include concentration at other
5 locations.

6 Q. Let me put it this way. Is it your
7 opinion that the convex shape would, would affect
8 light differently simply by swapping the location of
9 the detectors and LEDs?

10 MR. SMITH: Objection; form.

11 A. I just want to be clear that what is
12 generally understood here isn't a single simple focal
13 point of concentration. Light coming in from
14 different directions in this case would be understood
15 by a person of ordinary skill in the art to be
16 concentrated at different locations in this, in this
17 system. Light coming in pretty much along the normal
18 axis in the center would tend to be concentrated by
19 this particular idea of a lens towards the center,
20 underneath the lens. But light coming in from other
21 angles could be concentrated in other locations. The
22 lens provides a general benefit of light

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1 concentration, not just at the center.

2 Q. So it's your opinion that a light
3 can -- sorry -- that a lens can concentrate light in
4 more than one location?

5 MR. LARSON: Let me strike that.

6 Q. It's your opinion that a convex lens
7 can concentrate light to more than one location?

8 MR. SMITH: Objection; form.

9 A. It depends on the location of the
10 light source, yes.

11 Q. How about overall light entering the
12 lens, your -- is it your testimony that the light can
13 be concentrated at more than one location?

14 A. I think one of ordinary skill in the
15 art understands that light entry in a lens like this
16 is not 100 percent concentrated into a single
17 location.

18 Q. But overall light -- overall is the
19 light that enters a convex lens concentrated to one
20 particular location?

21 A. I think I just said one would
22 understand that light coming in from all angles is

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1 not going to be concentrated to a single location by
2 a convex lens. One of ordinary skill would know
3 that.

4 Q. And so when you use the term
5 "concentrating light," what do you mean?

6 A. It's deflecting using refraction and,
7 and the shape of the surfaces to deflect the light to
8 concentrate it at a desired location.

9 Q. Let me ask it this way. In, in
10 Inokawa Figure 2, does the convex lens result in more
11 light, more light reaching the center detector as
12 compared to a flat surface or less light reaching the
13 center detector?

14 MR. SMITH: Objection; form.

15 A. So Inokawa teaches that the lens
16 makes it possible to increase the light-gathering
17 ability. Incorporating a convex lens-like shape, as
18 described, increases the light-collection efficiency
19 which in turn leads to an enhanced signal-to-noise
20 ratio. The lens shape of Inokawa provides this by
21 refracting and concentrating light coming in.

22 Q. So earlier you were very clear that

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1 lens-like feature is capable of providing the
2 improvements in light-collection efficiency that
3 we've been discussing.

4 Q. And so why does the convex lens-like
5 feature in Inokawa result in improved
6 light-collection efficiency in Inokawa?

7 MR. SMITH: Objection; form.

8 A. I think one of ordinary skill in the
9 art, looking at this system and making some
10 assumptions about the index of refraction and the
11 geometry, would indicate, would believe that, that
12 some percentage of light reflected in from some of
13 those corpuscles would be refracted towards the
14 detector and that would lead to improvement in the
15 light-collection efficiency.

16 Q. Now, your testimony earlier about,
17 you know, examining the, the flow of light from one,
18 two, three, four, five, six, seven different
19 corpuscles, each reflecting light towards the center
20 and the particular effect a particular lens would
21 have, you don't provide any analysis like that in
22 your Declaration, do you?

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1 A. No. One of ordinary skill in the art
2 would understand that the general shape of a convex
3 lens provides the benefit that Inokawa describes in
4 the system that in general, there is an improvement
5 in the light-gathering efficiency that would lead to
6 an enhanced signal-to-noise ratio.

7 Q. But doesn't that depend on where the
8 detectors are under the, under the lens?

9 MR. SMITH: Objection; form.

10 A. So I think one of ordinary skill in
11 the art would believe and understand that it's
12 possible to obtain those benefits and that one would
13 then do some additional work in order to optimize the
14 system, but the capability of obtaining those
15 benefits is obviously present.

16 Q. So you testified the general shape of
17 a convex lens provides the benefit that Inokawa
18 describes and that there is an improvement in
19 light-collection efficiency. Are there some
20 circumstances where a convex lens placed over
21 sensors -- is there, are there some situations where
22 a convex lens placed over detectors and LEDs would

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1 power consumption and other features, but one of
2 ordinary skill in the art would know how to maneuver
3 within that, within that space.

4 Q. Okay. But your -- just to be clear,
5 your Declarations don't discuss this process of
6 adjusting sizes and shapes and locations that you've
7 been -- that you referenced?

8 MR. SMITH: Objection to form.

9 A. That's correct. One of ordinary
10 skill in the art would know how to do that.

11 Q. And so as I understand your
12 testimony, convex lens may concentrate light in many
13 different locations, correct? Is that, is that your
14 testimony?

15 MR. SMITH: Objection; form.

16 A. Yes, I'd say depending on the
17 location of the light, the orientation of the lens,
18 the curvature of the index, the actual location that
19 that light is deflected towards, it depends on all of
20 those things and it could be many different
21 locations.

22 Q. And does it depend on the location of

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1 art would understand that it's within their skills
2 and within the tools available to them to obtain
3 benefits such as using refraction and concentration
4 of the light to enhance the signal-to-noise ratio of
5 the system.

6 Q. Is it your testimony that, you know,
7 apart from extreme situations that a convex lens used
8 over detectors and LEDs is always going to improve
9 light concentration?

10 MR. SMITH: Objection; form.

11 A. Sorry to refer to extreme exception
12 so that it would be plainly obvious that there would
13 be no benefit without having to do any analysis.
14 There are, there is a universe of possible designs
15 here, some of which would provide benefits and some
16 of which would not.

17 Q. So a convex lens may provide benefits
18 in some situations and not others, depending on the
19 location of the LEDs and the detectors; is that fair?

20 MR. SMITH: Objection to form.

21 A. And the shape of the lens and
22 properties of the lens and a lot of other details.

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1 As I said, there's a universe of possible design
2 choices here. One of ordinary skill in the art would
3 have the knowledge to make good choices and then
4 follow that up with maybe some analysis or some
5 experimental optimization in order to provide the
6 benefits of, of improved pulse wave detection.

7 Q. In your Declaration, though, you
8 don't describe any of those, any of that experimental
9 optimization or other design choices. You take the
10 lens of Inokawa and basically put that lens onto
11 Aizawa, correct?

12 MR. SMITH: Objection; form.

13 A. So, no, I don't provide a sequence of
14 procedure steps for doing any sort of optimization.
15 I state plainly that a person of ordinary skill in
16 the art would find it obvious to combine these
17 elements and would know how to do so in a way that
18 obtained and provided some benefit.

19 Q. Do you think the light-collection
20 efficiency of a system is an important consideration
21 for a person of ordinary skill in the art designing a
22 noninvasive optical sensor?

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1 A. I think what follows in the rest of
2 that paragraph and the paragraph following that
3 indicate that what we're looking for here is a
4 transparent plastic material that is rigid and
5 provides the other optical and mechanical
6 characteristics that are important for this design of
7 this system. Acrylic is one representative choice
8 material, but it's not necessarily the only choice
9 that one would use.

10 Q. And in your combination, is the, is
11 the lens protrusion made of plastic at least? Can we
12 agree on that?

13 MR. SMITH: Objection; form.

14 A. It could be plastic. It could be
15 materials that you wouldn't necessary describe with
16 that word. Could be glass. Could machine and polish
17 a glass element. There's other materials one could
18 use.

19 Q. Okay. So I just want to understand
20 your opinions when you prepared this Declaration and
21 you signed these Declarations. Your opinion is that
22 a person of ordinary skill in the art would have been

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1 led to a lens or protrusion but it could be made of a
2 number of different materials. Is that, is that the
3 testimony you're giving now?

4 MR. SMITH: Objection.

5 A. I think one of ordinary skill in the
6 art would understand that you can obtain the benefits
7 associated with Aizawa and Inokawa with materials,
8 including acrylic and a number of other optical
9 transparent plastics.

10 Q. So what other -- but what you just
11 said is not in your report, correct, in your
12 declaration?

13 MR. SMITH: Objection; form.

14 A. So we do on Paragraph 99 describe
15 Nishikawa, another complementary reference.

16 Q. And in that paragraph you're
17 discussing acrylic, correct?

18 A. Acrylic is a representative
19 transparent plastic material that can be readily
20 transformed into various shapes. I do not say it's
21 the only such material one would ever use or consider
22 using.

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1 Q. Where do you say they were
2 representative in Paragraph 99?

3 MR. SMITH: Objection; form.

4 Q. You don't, you don't the word
5 "representative" in Paragraph 99.

6 Can we agree on that?

7 A. I think we can agree on that.

8 Q. Okay. What are you looking at now?

9 A. Just looking for other places where I
10 describe the benefits of this combination, where I
11 might have made some comments about the materials.

12 Reading in Aizawa Paragraph 13, this
13 plate is described as a plate-like member. It
14 doesn't explicitly require the use of acrylic.

15 Q. You're looking at Aizawa now. My
16 question is about your Declaration, Dr. Kenny.

17 A. I know. This is the context for the
18 choice of materials that one of ordinary skill in the
19 art would consider for making the structure shown in
20 the figure we've been referring to on page 55.

21 Q. So let me -- I just want to
22 understand your opinions when you wrote this and

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1 Q. If you're asking me what I'm asking
2 about, I'm asking about your -- the basis for your
3 assertion that the modification from the figure on
4 the bottom left to the figure on the bottom right
5 would increase light-gathering ability.

6 What, what is your basis for that
7 assertion?

8 A. So the objective of this device is
9 for light leaving the LED to enter the tissue,
10 scatter off of some corpuscles or other blood
11 carrying members, and be reflected towards the
12 detectors and the objective is to improve the
13 light-gathering efficiency of, of that arrangement by
14 providing a convex lens where there's curvature of
15 that lens positioned over the detector between the
16 detector and where the reflection might be taking
17 place.

18 I think one of ordinary skill in the
19 art would understand that it's possible for a design
20 of this type to provide improved light-gathering
21 efficiency.

22 Q. You testified before that a convex

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1 lens may have many locations where there's light
2 concentration, correct?

3 A. That's correct.

4 Q. So where would the light collection
5 locations be in your bottom figure right?

6 MR. SMITH: Objection; form.

7 A. So light reflecting off of corpuscles
8 in the tissue nearby would be reflected back into the
9 structure at many locations.

10 Q. Can you tell me where those locations
11 are?

12 A. Well, I'll pick one. For example,
13 the red detector on the right is one that I'm
14 particularly interested in, in this design and
15 there's the curvature of the lens that's provided
16 over that location, would provide some enhanced
17 light-collection efficiency because of the way of --
18 the refraction would, would change the pathways of
19 the light in that region.

20 Q. Are there any other light -- are
21 there other places where you opine that you believe
22 there would be light --

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1 MR. LARSON: Strike that.

2 Q. Are there other places where light
3 collection would exist?

4 A. Sure, yes, maybe the detector on the
5 left as well.

6 Q. Anywhere else?

7 A. It could be true at other locations
8 in between.

9 Q. Can you tell me where those locations
10 are?

11 A. At the location of the particular
12 corpuscle and the various distances and angles but
13 the, the general characteristic of a convex lens is
14 that the refraction of that lens can provide some
15 improved light-gathering efficiency.

16 Q. Can you tell me -- apart from the
17 location of the detectors, can you tell me where
18 these other alleged light-collection efficiency
19 locations would be?

20 A. So it depends on the location of the
21 reflected corpuscle or the corpuscle being reflected
22 from, but imagining that there are many of them

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1 increase in light concentration at the detectors

2 relative to other areas?

3 MR. SMITH: Objection; form.

4 A. So if my goal was to have enhanced,
5 you know, optimized light collection at a particular
6 location, I would need to know the exact location of
7 the reflecting corpuscles. In the absence of that
8 precise knowledge, I think one of ordinary skill in
9 the art would design a lens of this general shape,
10 perhaps details as far as exact curvature and so on
11 to be worked out, but this general shape to in
12 general improve the light-collection efficiency at
13 the location of the detectors.

14 Q. So you can't tell me looking at this
15 figure, whether the light collection -- the increase
16 in light-collection efficiency at the detectors would
17 be greater than the alleged light-collection
18 efficiency anywhere else; is that correct?

19 MR. SMITH: Objection; form.

20 A. It would depend on the details of the
21 radius of curvature which is shown figuratively here
22 but not in precise detail. It would depend on some

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1 single focal point. It produces a, a sort of
2 concentration over a region.

3 Q. What region?

4 A. It depends on the shape of the lens
5 and the thickness of the lens and other parameters,
6 distance from the, the face of the lens to the
7 locations of the detectors.

8 Q. How about the, the, the lens in your
9 combination, the figure at the bottom right below
10 Paragraph 97?

11 A. Yeah, I would say there's some, given
12 the arrangement of the corpuscles as the reflecting
13 objects in the space all around underneath that lens,
14 that there would be some improvement in the light
15 concentration at pretty much all of the locations
16 under the curvature of the lens.

17 Q. And so when you said the convex shape
18 results in a concentration over a region, your
19 opinion is that the convex shape in your combination
20 in the figure on the right below Paragraph 97 would
21 increase light concentration at all the locations
22 below the curvature of the lens; is that correct?

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1 A. -- if we go all the way to the edge
2 from like the corner at the end of the cover, for
3 example, where there's no nearby curvature to help
4 redirect the light, there would be less light there
5 and more light inwards of that.

6 Q. Because the light is being directed
7 from an edge more towards the center, correct?

8 A. There's a lot of different things
9 going on for different rays of light. I'd say some
10 of the light coming to that edge has a better chance
11 of being refracted inwards because of the curvature
12 versus a flat plate. That's not true all the way at
13 the edge but it is inwards from there. And the
14 refraction also has the benefit of, of increasing the
15 concentration of the light. So it's a capture and
16 refraction benefit.

17 Q. So when it's referenced a moment ago,
18 the flat plate, your cover on the very ends is flat,
19 correct?

20 A. In this example, yes.

21 Q. Why did you include -- why did you
22 make the ends, the exterior of the cover flat?

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1 MR. SMITH: Objection; form.

2 A. I can think of a number of reasons
3 for that. If we look at the example provided by
4 Nishikawa, which illustrates a lens feature shaped
5 more or less of the same sort for an LED package,
6 when I read Nishikawa and look at that reference, my
7 understanding is that the design here is intended to
8 provide curvature in the lens where it can do the
9 most good and otherwise try to avoid excess use of
10 material in order to create curvature in locations
11 where it wouldn't do any good. That's my
12 interpretation of some of what's going on in
13 Nishikawa.

14 Q. Okay. So if you look at Figure 6
15 from Nishikawa which is under your Paragraph 99, is
16 that what you're referring to?

17 A. Yes.

18 Q. One that has a similar shape to the
19 shape of your cover in the combination of
20 Aizawa-Inokawa?

21 A. Yes.

22 Q. Why would a person of ordinary skill

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1 in the art be motivated to include the shape Aizawa
2 as part of the -- sorry.

3 Why would a person that's skilled in
4 the art be motivated to include the shape Nishikawa
5 as a part of your combination?

6 MR. SMITH: Objection; form.

7 A. Could you repeat that?

8 Q. Yeah. Why would a person of ordinary
9 skill in the art be motivated to include the shape of
10 Nishikawa in your combination of Aizawa and Inokawa?

11 A. So Nishikawa is a representative
12 example of a manufacturable molded lens with similar
13 optical and mechanical requirements plus details of
14 how to go about the manufacturing process that I
15 would regard as helping me do a good job of obtaining
16 the benefits at a modest cost.

17 Q. And so you think a person of ordinary
18 skill in the art -- so it's your opinion that a
19 person of ordinary skill in the art would have relied
20 on --

21 MR. LARSON: Strike that.

22 Q. While we're looking at Figure 6 below

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1 curvature, one can save material, and maybe have a
2 lighter weight structure and a less expensive
3 structure by simply having curvature where it's
4 useful.

5 Q. Your curvature extends far beyond the
6 detectors, though, correct?

7 A. This is, again, not intended as a
8 precise engineered drawing but as a representative
9 example of the kinds of shapes that one might arrive
10 at with ordinary skill in the art having viewed
11 Inokawa in view of Aizawa or vice versa, Aizawa and
12 Inokawa together and Inokawa.

13 Q. I hear an explanation but I guess
14 first I just want a answer to my question. Your
15 curvature on the cover as shown in the figure to the
16 right under Paragraph 97, that curvature extends far
17 beyond the detectors, correct?

18 MR. SMITH: Objection; argumentative.

19 A. We're talking millimeters here. And,
20 again, I didn't intend for any precise aspect ratio
21 relationship to be represented in this figure. This
22 is merely representative of what I think a person of

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1 ordinary skill in the art would arrive at in the
2 context of the prior art and the problem to be
3 solved.

4 Q. So a person of ordinary skill in the
5 art looking at Nishikawa and Inokawa and Aizawa might
6 end up with a number of different lens shapes. Is
7 that your testimony?

8 MR. SMITH: Objection; form.

9 A. Within the general category of convex
10 lenses, yes.

11 Q. Can you explain, explain to me the
12 different lens shaped that a person of skill in the
13 art might chose to use in a combination like this?

14 MR. SMITH: Objection; form.

15 A. So there are many subcategories of
16 the convex lens-like shape that we've represented
17 here. One might, for example, have a spherical lens.
18 One might in a different geometry perhaps have a
19 cylindrical lens. There's many, many shapes.

20 Q. And how would a person of skill in
21 the art go about choosing which shape to use when
22 combining Aizawa and Inokawa?

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1 A. So it could be done by trial and
2 error trying out different shapes, different detector
3 positions, different spacings and so on. It could be
4 done rudimentary ray trace analysis but, again,
5 remembering that the light source is diffuse and not
6 a point source or a comminuted source. One always
7 ends up with a situation where the light coming
8 through the lens is going to be not concentrated on a
9 signal point. But, but still distributed because of
10 the characteristics of the incoming source. One is
11 only attempting to obtain some benefit in the
12 light-collection efficiency so as to improve the
13 signal-to-noise ratio.

14 Q. And so your testimony is that when
15 diffuse light goes through a convex shape, the light
16 coming through is not going to be concentrated on a
17 signal point, and I think you testified earlier that,
18 in fact, it would be concentrated on the entire
19 region beneath the convex lens; is that correct?

20 MR. SMITH: Objection; form.

21 A. There would be concentration across
22 that surface, I think. If the word "concentration"

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1 length. So the refractive effect will lead to a
2 short mean of the path on average of the mean.

3 Q. So what you're showing here is
4 that -- so when --

5 MR. LARSON: Sorry, strike that.

6 Q. So what you're discussing here when
7 you say a mean path length, you're talking about the
8 path on average; is that is that fair?

9 MR. SMITH: Objection; form.

10 A. So a mean path length mean the same
11 as an average patent length, yeah.

12 Q. Is that how you're understanding it?

13 A. My understanding, yes, would be if I
14 repeated this analysis for a multitude of path
15 lengths, I would find that the majority of them would
16 have a shorter path length.

17 Q. If you go down to Paragraph --
18 Paragraph 119, you say, "In more detail, I noted
19 above for [1d] how the lens/protrusion of Inokawa,
20 which is used to modify Aizawa's cover, provides a
21 condensing function by refracting the light passing
22 through it."

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1 correct?

2 A. That sentence doesn't exclude that
3 there would be light concentration taking place at
4 other locations. It merely says that there will be
5 more light gathered and refracted towards the
6 light-receiving cavities than would have been the
7 case with a flat plate.

8 Q. Is it your understanding that light
9 can be thought to --

10 MR. LARSON: Strike that.

11 Q. If the light is being refracted
12 towards the light-receiving cavities of Aizawa, isn't
13 the light being refracted away from somewhere else?

14 A. So, you know, as we said, the lens is
15 not amplifying the light. It's capturing and
16 redirecting the light. It -- because of its shape is
17 able to capture more light due to the convex shape,
18 and it's able to increase the concentration of the
19 light directed towards the cavities under the regions
20 where the curvature of the lens is present.

21 Q. Right. And my question, though, is
22 slightly different. I understand that you're saying

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1 that it will increase the light concentration towards
2 the detectors and the region in between the
3 detectors. I'm asking where is that light being
4 directed away from? If total light amount is not
5 going up and you're refracting light towards the area
6 between the detectors, including to the detectors,
7 where is that light being refracted from?

8 A. I think if you -- again, the details
9 would depend on where the corpuscles were, and there
10 could be some variation from instance to instance.
11 But on average, if you look at where the light was
12 refracted across this surface, there would be a
13 reduction in the amount at the perimeter, and an
14 increase as you come underneath the curvature towards
15 the center. There is a region at the perimeter where
16 there would be a decrease. And maybe just to help
17 with this, we're looking at a 2D picture of a 3D
18 object, which artificially suppresses the amount of
19 space -- or the amount of surface at the perimeter
20 relative to the inner area.
21 So there's a lot of area from which
22 to draw light away in towards the center.

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1 Q. And so with the convex shape in your
2 combination, I think you testified just now that
3 there would be a reduction in the amount of light at
4 the perimeter and an increase as you come underneath
5 the curvature towards the center; is that correct?

6 A. Maybe just to be precise, if you
7 looked across -- if you looked on the example on the
8 right and you had a way of measuring the light
9 intensity from centered all the way to edge and you
10 could do it for enough different examples of the
11 corpuscle arrangements that you could average out
12 those artifacts, you would see more light in the
13 center than at the outer edge in this example.

14 Q. And that's because light's being
15 directed towards the center and away from the edge,
16 correct?

17 A. Among other things, yes, that's a
18 part of why. Also, as we've discussed, this
19 protruding lens is able to capture more light coming
20 in at a weak angle that is additive to this effect.

21 Q. So it sounds like there's two
22 considerations here. One is the convex lens in

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1 general would direct more light to the center; the
2 other is your testimony that a protruding lens
3 overall would capture more light. Am I capturing
4 your testimony correctly?

5 A. I think one of ordinary skill in the
6 art would appreciate that those are both true,
7 simultaneously, that you have the, the, the general
8 lens-like shape of the convex lens provides
9 refraction which allows additional concentration of
10 light and light-collection efficiency, and that the
11 protrusion provides an opportunity to capture some
12 light that would otherwise not be captured.

13 Q. So just so we're clear, though, if
14 you put aside your reasoning that the protrusion
15 would otherwise provide an opportunity to capture
16 more light that otherwise would be captured, the
17 light that's being focused more towards the center is
18 being directed away from the exterior, correct?

19 A. So the relative amounts of that -- of
20 those two effects and the relative sizes of those
21 effects, center of the edge, would depend on the
22 details of the curvature design. You know, if we had

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1 a spherical example or this example or some other
2 examples there would be different amounts of these
3 two effects at different locations. So it's hard to
4 give a general accurate answer.

5 Q. Oh, and my question, to be clear, I'm
6 trying to have you focus on just one of the effects.
7 So just for the -- and, you know, you can go on and
8 provide more testimony, you can provide testimony
9 about the other fact that you sort of -- but focusing
10 just on the first effect, the fact that the convex
11 lens will direct more light toward the center means
12 that it will be directing more light away from the
13 sides, correct?

14 A. I think one of ordinary skill in the
15 art looking at this illustration on the bottom right
16 of Page 55 would understand that both effects are
17 present, but to the extent we're focused just on the
18 refraction effect and not the light capture effect,
19 that the, the distribution of light on that surface
20 would be shifted from the edge towards the center
21 somewhat depending on the details of the shape.

22 Q. Let me ask you about the -- this

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1 other effect, then, and I guess my question would be
2 how would a person of skill in the art have balanced
3 the two effects overall what, what the impact would
4 be on where light falls in the sensor?

5 MR. SMITH: Objection; form.

6 A. These are two effects combined with
7 many other effects that one of ordinary skill working
8 on this problem would be balancing the lens design
9 against all of those other considerations. There
10 isn't a simple answer to that.

11 Q. Okay. And to be clear, your
12 Declarations don't discuss this effect of capturing
13 more light due to the convex shape, correct?

14 MR. SMITH: Objection; form.

15 A. So it's, I think, one of the
16 characteristics of a convex lens that one of ordinary
17 skill in the art would understand, is able to capture
18 light at angles of incidence that a flat plate might
19 not capture. That's, I think, within what a person
20 of ordinary skill in the art would know.

21 Q. Okay. But you didn't discuss that in
22 your Declarations; is that fair?

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1 A. That's correct.

2 Q. So I want to ask you a few questions
3 going back to the mean path length limitation just to
4 make sure I understand your figures. One moment
5 here.

6 So this is back at Paragraph 119 --
7 well, actually Paragraph 20. I want to ask you about
8 the figure below Paragraph 120. So is the dark blue
9 layer the cover, essentially, the flat cover?

10 A. The intent of the figure that's right
11 at the bottom of 120 is simply to overlay the two
12 figures above Paragraph 120 to help clarify the
13 difference in the two path lights.

14 Q. Okay. And in both figures the dark
15 blue is a flat cover, correct?

16 A. So in the left figure the dark blue
17 is the flat cover. The lighter blue is reflector
18 representing the shape of the combination of the two
19 references. And in the combined figure they are just
20 simply plates on top of each other for simplicity in
21 visualizing the length of the rays.

22 Q. And the black rectangle is a

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1 Q. Are you waiting for me to re-ask the
2 question?

3 A. I'm just going back because we're
4 talking about the wall in a couple of different
5 locations in this Declaration, just making sure we're
6 referring to the same thing in the same way. Forms a
7 wall -- all right. Okay. So all right.

8 Paragraph 162 in this first sentence,
9 I understand why you're asking. It's -- I think
10 really the root cause here is a typo and perhaps some
11 unnecessary commas. I think one of ordinary skill
12 understands that the holder including the wall,
13 everything about the holder is, is made of an opaque
14 material. That's clearly the intent in Aizawa. He
15 describes rays that, that can reach the detectors if
16 they can somehow find those tapered openings, but not
17 if they pass-through any part of this holder so the
18 entire holder is opaque.

19 Q. Are you correcting a typo? I'm
20 sorry, go ahead.

21 A. And including all the surfaces of the
22 holder, so I think where the last instance of the

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UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

| | | |
|---------------------|---|--------------------------|
| APPLE INC., |) | |
| |) | IPR NO. 2020-1520 |
| Petitioner, |) | US PATENT NO: 10,258,265 |
| -against- |) | IPR NO. 2020-1537 |
| |) | US PATENT NO: 10,588,553 |
| MASIMO CORPORATION, |) | |
| |) | IPR NO. 2020-1539 |
| Patent Owner. |) | US PATENT NO: 10,588,554 |
| |) | |

VIDEO-RECORDED DEPOSITION OF
THOMAS WILLIAM KENNY, JR. PH.D.

VOLUME 2

Zoom Recorded Videoconference

04/23/2021

9:02 a.m. (PDT)

REPORTED BY: AMANDA GORRONO, CLR

CLR NO. 052005-01

DIGITAL EVIDENCE GROUP
1730 M Street, NW, Suite 812
Washington, D.C. 20036
(202) 232-0646

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| Masimo Ex. 2007 Apple v. Masimo, IPR2021-00193 |
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1 a person of ordinary skill in the art would -- who
2 wants to apply the teaching of Inokawa, would
3 consider the shape of the lens, the thickness index,
4 curvature when applying Inokawa to a particular
5 sensor configuration; is that fair?

6 A. Yeah. So, I mean, Inokawa is
7 providing a concept of convex lens-like shape that
8 makes it possible to increase the light-gathering
9 ability. One of ordinary skill in the art would
10 understand that, that what Inokawa provides is
11 descriptive and not precise; that one shouldn't
12 attempt to copy and paste the exact geometry of
13 Inokawa into a different system and expect it would
14 automatically be the right solution. One of ordinary
15 skill in the art would do the work to improve the
16 design in order to improve the opportunity for
17 increased light collection efficiency. And --

18 Q. And so far I just want to be sure
19 we're clear, you've discussed that a person of
20 ordinary skill in the art would consider the shape of
21 the lens, its thickness index curvature, the length,
22 width and thickness of the lens.

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1 Is there anything else that a person
2 of ordinary skill in the art would consider when
3 applying the teaching of Inokawa to a particular
4 device?

5 A. Not that I can think of here. These
6 are the routine parameters that would specify the
7 shape of a lens that can be selected in order to
8 obtain certain optical properties. This is
9 straightforward for one of ordinary skill in the art.

10 Q. And you agree that Inokawa doesn't
11 discuss the shape of the lens, its thickness index,
12 curvature, the length, width and thickness of the
13 lens, correct?

14 A. I don't believe that is precisely
15 stated in Inokawa.

16 MR. SMITH: Objection to form.

17 Q. And you don't discuss any of those
18 things in your Declarations, correct?

19 A. Precise numbers for any of those
20 parameters, no. None of those are discussed.

21 I believe there are claims in one of
22 the specifications that describe something related to

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1 Q. My question is: Can you recall any
2 prior art reference that has a physiological sensor
3 with multiple detectors under a convex cover?

4 Sitting here during the deposition,
5 can you recall any such reference?

6 A. Not off the top of my head.

7 Q. So looking, again, at your
8 combination of Aizawa and Inokawa on Page 55 of your
9 Declaration as previously marked Exhibit Apple 1003,
10 can you pull that up again?

11 A. Page 65?

12 Q. Yes -- or Page 55, the bottom of
13 Page 55, yeah.

14 A. Uh-uh. Okay.

15 Q. In the bottom right figure, which
16 is -- the bottom right figure is your, your, your
17 combination of Aizawa and Inokawa, correct?

18 A. That's correct.

19 Q. In that bottom right figure, if one
20 were to move the detectors slightly toward the
21 center, would a person of ordinary skill in the art
22 expect an increase or a decrease in signal strength

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1 at the detectors?

2 MR. SMITH: Objection; form.

3 A. So it's not obvious because part of
4 the answer depends on the depth of the likely
5 locations of the corpuscles that are going to provide
6 the diffuse reflection, and I don't have any
7 dimensions here to scale that against. It would be a
8 judgment of sort of aspect ratio between those
9 distances and the distances here. It could be true,
10 it might, might not be. It would depend on the other
11 dimensions.

12 Q. This is your figure, correct?

13 A. Yes.

14 Q. You created this figure?

15 A. Yes.

16 Q. Okay. And your testimony is that
17 you're not able to tell me whether in the figure you
18 created the signal strength can go up or down if the
19 detectors were moved closer to the center?

20 MR. SMITH: Objection; form.

21 A. That's correct. The figure was
22 intended to illustrate the general concept of the

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1 combination of a protruding convex cover, following
2 the teachings of Aizawa and Inokawa, and that the
3 detailed implementation would be straightforward work
4 from one of ordinary skill in the art that would
5 involve the specific positioning of the elements.

6 Q. What if the, what if the sensor was
7 placed in the same location for both series of
8 measurements, same environment, and the only change
9 was that the detectors are placed slightly towards
10 the center, would a person of ordinary skill in the
11 art expect an increase or a decrease in signal
12 strength?

13 MR. SMITH: Objection; form.

14 A. You know, without knowing anything in
15 a quantitative nature about the sizes of actual
16 dimensions of the objects and the expected depth in
17 the tissue where the corpuscles are likely to be
18 providing the strongest reflection, that's an un- --
19 that's an ill-posed question.

20 Q. So you don't know the sizes of the
21 dimensions of the combination that you proposed in
22 the figure in the right-below Paragraph 97?

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1 MR. SMITH: Objection; argumentative.

2 A. The figures are intended to
3 illustrate how one might combine a protruding
4 lens-like shape, convex lens-like shape with the
5 other details of Aizawa so as to improve light
6 collection efficiency, leading to enhanced
7 signal-to-noise and ultimately more reliable
8 detection that one of ordinary skill in the art would
9 take this example, these examples in these pieces of
10 prior art and apply them to specific dimensions and
11 specific details in a particular application.

12 Q. So I think that was a yes, but just
13 to make -- let me make sure, you don't know the
14 specific dimensions of the combination that you
15 presented in the figure on the right-below
16 Paragraph 97; is that correct?

17 MR. SMITH: Objection; form.

18 A. This figure takes the structure from
19 Aizawa and adds a convex lens-like shape per Inokawa
20 in a way that suggests how these would be combined so
21 as to improve performance. I don't have the
22 dimensions from Aizawa's specification in terms of

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1 the lateral dimensions, the vertical dimensions,
2 thickness of the plate. And without any of that
3 information, I can't answer an absolute quantitative
4 question in the context of vague input parameters.

5 Q. And you testified you wouldn't be
6 able to -- you testified a person of ordinary skill
7 in the art would not be able to understand the impact
8 of signal strength when moving the detectors towards
9 the center for the additional reason that you don't
10 know the expected depth in the tissue where the
11 corpuscles are likely to provide reflection; is that
12 correct?

13 MR. SMITH: Objection; form.

14 A. I don't think so. I think what I
15 said is that you would need that information in order
16 to answer those questions and that one of ordinary
17 skill in the art would know how to apply that
18 information to the situation.

19 Q. So in your combination, did you have
20 in mind any particular depth in the tissue where the
21 corpuscles are likely to provide reflection?

22 MR. SMITH: Objection; form.

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1 Q. And so a person of ordinary skill in
2 the art combining the teachings of Aizawa and Inokawa
3 including a, a convex cover may end up with a
4 configuration of detectors and LEDs that's different
5 than the configuration in Aizawa; is that correct?

6 MR. SMITH: Objection; form.

7 A. So Aizawa does not specify precise
8 locations. I assume that someone building a product
9 would end up specifying precise locations. It's hard
10 to say whether a precise location is different than
11 the absence of that. Obviously I don't know how to
12 compare those.

13 Q. So what I'm asking is because there
14 is a convex surface now included in Aizawa, it sounds
15 like your testimony is that a person of ordinary
16 skill in the art would need to take into account all
17 these considerations that you've been, that you've
18 been testifying to, and as a result of that, may
19 decide that it's necessary to change the
20 configuration of LEDs and detectors; is that correct?

21 MR. SMITH: Objection; form.

22 A. I think one of ordinary skill in the

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1 art would combine the teachings of Aizawa and Inokawa
2 based on their understanding of the principles and
3 objectives of their process and that includes, I
4 think, certainly going from cartoons to real designs,
5 which would mean adding dimensions and real
6 specifications to these illustrations.

7 Q. And that may result in a different
8 configuration of LEDs and detectors; is that fair,
9 than what's is shown --

10 MR. SMITH: Objection; form.

11 Q. And that may result in a different
12 configuration of LEDs and detectors from that shown
13 in Aizawa's figure; is that fair?

14 MR. SMITH: Objection; form.

15 A. Even Aizawa considers a number of
16 configurations of detectors and emitters as part of
17 the teachings. So I think one reading Aizawa and
18 recognizing that Aizawa considers different numbers
19 of detectors and different combinations, that would
20 be within the range of applying the teachings of
21 Aizawa and Inokawa.

22 Q. But it's possible that because of the

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1 using the alternating pulse scheme that we discussed
2 briefly a few moments ago. That's a choice for the
3 designer, but you'll be measuring the same -- those
4 two signals during the same period of time.

5 Q. All right. Let me ask a different
6 question about Aizawa. Aizawa's goal is to address
7 problems associated with realtime measurement of
8 heart rate, correct?

9 MR. SMITH: Objection; form.

10 A. Sure, that's somewhere in the field
11 of the invention statement.

12 Q. Okay. And in contrast, Inokawa's
13 data transmission approach requires the user to
14 remove the monitoring device and connect it to a base
15 station to transfer data, correct?

16 MR. LARSON: Well, let me, let me
17 back up to Aizawa.

18 Q. Okay. So a person of ordinary skill
19 in the art would have understood that Aizawa's
20 wireless transmitter is used to transmit pulse rate
21 data to a display, correct?

22 A. You're reading that from a paragraph

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1 A. At that time, that's correct, yes.

2 Q. And Inokawa's approach is one in
3 which the user would have to remove the monitoring
4 device and connect it to a base station to transfer
5 data, correct?

6 MR. SMITH: Objection; form.

7 A. That's correct.

8 Q. And so Inokawa's base station data
9 transmission approach would mean that Aizawa would no
10 longer be able to provide realtime monitoring and
11 display of heart rate, correct?

12 MR. SMITH: Objection; form.

13 A. So the combination of Aizawa and
14 Inokawa doesn't explicitly require that one adopt the
15 base station and wrist sensor configuration that is
16 one of the embodiments in Inokawa. Inokawa describes
17 optical data transmission, mentions the existence of
18 wireless data transmission and provides the use of a
19 second LED both for sensing of physiological
20 parameters and motion and also for use of that second
21 LED to support the communication of the data.

22 Q. Let's go to Paragraph 80 of your

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Thomas Kenny, Jr. Ph.D.

Page 1

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

| | | |
|---------------------|---|--------------------------|
| APPLE INC., |) | |
| |) | |
| Petitioner, |) | US PATENT NO: 10,588,553 |
| |) | IPR NO. 2020-1536 |
| -against- |) | |
| |) | US PATENT NO: 10,588,554 |
| MASIMO CORPORATION, |) | IPR NO. 2020-1538 |
| |) | |
| Patent Owner. |) | |
| |) | |

VIDEO-RECORDED DEPOSITION OF
THOMAS WILLIAM KENNY, JR. PH.D.

VOLUME 1

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04/24/2021

9:01 a.m. (PDT)

REPORTED BY: AMANDA GORRONO, CLR
CLR NO. 052005-01

DIGITAL EVIDENCE GROUP
1730 M Street, NW, Suite 812
Washington, D.C. 20036
(202) 232-0646

Masimo Ex. 2008
Apple v. Masimo, IPR2021-00193

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1 with the palm of the hand (indicating).

2 Q. Okay. And so some of your previous
3 testimony, you had those switched?

4 A. That's correct. In the last section,
5 I was partly talking about Paragraph 24 and the
6 relationship of the bones to whether or not a person
7 would be comfortable or not, so I, I got myself kind
8 of wound into a rabbit hole there. Let's, if we
9 could, please consider that some of that testimony
10 was using front and back, in a mixed-up way, so we
11 can get back on track now. The back of the hand and
12 the back of the wrist are on the same side.

13 So Figure 3(a) is related to a
14 measurement of the sensor mounted on the back of the
15 wrist where we would normally wear a watch. And 4A
16 show a sensor with a convex protrusion as compared
17 with a sensor element that has a flat cover.

18 Q. And do you have an understanding of,
19 of where the device is being -- on which side the
20 sensor is in Figure 4?

21 A. I think most of the specification is
22 referring to the sensor mounted on the back of the

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1 wrist, so I'm -- it doesn't say explicitly, but I'm
2 going to make that judgment. I think one of ordinary
3 skill in the art would think Figure 4 applies to a
4 sensor mounted on the back of the wrist.

5 Q. Okay. So a few moments ago, before
6 we went to the break, you testified you believe the
7 performance shown in Figure 3 and 4A were comparable.
8 And my question for you is: Does that help you
9 understand whether Figure 3A tested a device with a
10 convex surface?

11 MR. SMITH: Objection; form.

12 Q. Does that help you understand that
13 Figure 3A tested a sensor with a convex surface?

14 MR. SMITH: Same objection.

15 A. Back side of user's wrist -- I think
16 that's the most reasonable interpretation. It's not
17 clearly stated in Paragraph 24, which describes
18 Figure 3A, but in the context of the specification, I
19 believe that the element being tested in Figure 3(a)
20 and 3B has a convex cover, and what's being
21 illustrated is that it's better to mount the sensor
22 on the back of the wrist than on the front of the

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UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

| | | |
|----------------------|---|--------------------------|
| _____ APPLE INC., |) | |
| |) | |
| Petitioner, |) | US PATENT NO: 10,588,553 |
| |) | IPR NO. 2020-1536 |
| -against- |) | |
| |) | US PATENT NO: 10,588,554 |
| MASIMO CORPORATION, |) | IPR NO. 2020-1538 |
| |) | |
| Patent Owner. |) | |
| _____ |) | |

VIDEO-RECORDED DEPOSITION OF
THOMAS WILLIAM KENNY, JR. PH.D.
VOLUME 2

Zoom Recorded Videoconference

04/25/2021

8:59 a.m. (PDT)

REPORTED BY: AMANDA GORRONO, CLR
CLR NO. 052005-01

DIGITAL EVIDENCE GROUP
1730 M Street, NW, Suite 812
Washington, D.C. 20036
(202) 232-0646

Masimo Ex. 2009
Apple v. Masimo, IPR2021-00193

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1 the five giant boxes of paper that were printed and
2 shipped.

3 Q. Yeah, let me -- I'll direct you to
4 previous exhibit. Going to be referring to -- one --

5 A. I found it in Folder 79, if that
6 helps.

7 Q. Just to make it a cleaner -- let's
8 do, if you don't mind, Folder 43, and that's
9 previously marked Apple Exhibit 1004 in IPR1536.

10 (Whereupon, Exhibit 1004, Curriculum
11 Vitae of Dr. Thomas W. Kenny was identified.)

12 A. Okay.

13 Q. Okay. Just a moment here. Okay.
14 Can you describe for me what background you have in
15 optics?

16 A. So I have a bachelor's degree in
17 physics and a Ph.D. in physics. I've worked on
18 sensors and systems, including optical systems, for
19 many years.

20 Q. Have you, have you done any work on
21 physiological sensors?

22 A. So there is work on pressure sensors,

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1 infrared sensors, accelerometers, temperature
2 sensors, all of which could be used for physiological
3 sensing.

4 Q. But did the sensors you worked on --
5 were the sensors you worked on physiological sensors?

6 MR. SMITH: Objection; form.

7 A. I'm not recalling anywhere we
8 specifically built a system to perform physiological
9 measurements. It's possible I'm overlooking
10 something but it's been a long career. Sorry. I'm
11 not recalling any anything.

12 Q. And the sensors you just mentioned,
13 you mentioned pressure sensors, infrared sensors,
14 accelerometers and temperature sensors, were all of
15 those optical sensors or just some of them?

16 MR. SMITH: Objection to form.

17 A. Some of them were, some of them were
18 optical sensors.

19 Q. Can you explain which, which were
20 optical?

21 A. There were infrared sensors. There
22 was something else briefly in my mind that I've

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1 forgotten already. Sorry, but, yeah, the infrared
2 sensors would, I think, be included in the category
3 of optical sensors.

4 Q. And, and can you explain to me the
5 work you did on infrared sensors?

6 A. We developed various high performance
7 infrared sensors. I mean, I can give you a lecture
8 on what went on. I don't think you're interested in
9 all of that.

10 (Simultaneous crosstalk.)

11 A. We used micromechanical elements to
12 detect infrared signals through the absorption of the
13 infrared radiation and the effect of that absorbed
14 energy on the mechanical structures, reflections and
15 displacements in particular.

16 Q. Is there a particular part of the CV
17 I could look to, to see your experience with regard
18 to infrared sensors?

19 MR. SMITH: Objection; form.

20 A. Page 36 includes a reference to some
21 conference papers in that area. It may be better
22 Page 13, for example.

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1 Q. Were these infrared sensors designed
2 to be used in any particular environment?

3 A. So we were exploring the tradeoffs
4 between design and performance relative to the
5 state-of-the-art for detection of infrared radiation
6 without a cooled detector element and the context, at
7 least from the standpoint of our sponsors, was
8 thermal infrared imaging.

9 Q. And was there some potential
10 practical application that the research was directed
11 to?

12 A. It's fundamental work, so it would
13 have a range of applications. But our sponsors were
14 interested in night vision.

15 Q. And were you responsible for the
16 design of the sensors, that were the subject of that
17 work?

18 MR. SMITH: Objection; form.

19 A. Yes.

20 Q. And so you designed the sensors being
21 used in those studies?

22 MR. SMITH: Objection; asked and

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1 answered.

2 A. I did, yes.

3 Q. Can you just describe to me at a high
4 level the structure of those sensors?

5 A. So, there was a membrane with a thin
6 absorbing film on the surface of a cavity that was
7 coupled to a displacement sensor on the opposite
8 side. And the absorption of thermal energy from the
9 incoming infrared radiation caused heating of the
10 cavity, thermal expansion of the gas in the cavity
11 and displacement of a nearby element.

12 Q. Did the sensors use LEDs?

13 A. We might have performed some
14 characterization using LEDs.

15 Q. Do you recall one way or another?

16 A. So we used optical fibers and laser
17 light sources as part of the characterization
18 instrumentation around that work, which also included
19 lenses, optics, components, displacements, you know,
20 all of the normal things you'd find on an optical
21 table were all part of that work.

22 Q. Okay. But you don't recall one way

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1 or another whether those sensors used LEDs; is that
2 correct?

3 A. So there were no LED --

4 MR. SMITH: Objection.

5 A. There were no LEDs in the sensor. We
6 might have had LEDs as part of the hardware and tools
7 we used to characterize the system, align the optics,
8 and prepare for the measurements.

9 Q. Have you ever designed a
10 physiological sensor?

11 MR. SMITH: Objection; form. Asked
12 and answered.

13 A. I don't recall ever designing a
14 physiological sensor in the context of the discussion
15 we've had.

16 Q. Have you ever designed a pulse
17 oximetry sensor?

18 A. I have not.

19 Q. Did you ever go through the process
20 of trying to determine the impact of a particular
21 modification on a physiological sensor?

22 MR. SMITH: Objection; form.

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Page 1

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

- - - - -x

APPLE, INC.,

Case IPR2020-01520

U.S. Patent 10,258,265

Petitioner,

Case IPR2020-01539

U.S. Patent 10,588,554

-against-

Case IPR2020-01537

U.S. Patent 10,588,553

MASIMO CORPORATION,

Case IPR2020-01536

U.S. Patent 10,588,553

Patent Owner.

Case IPR2020-01538

U.S. Patent 10,588,554

- - - - -x

VIDEO-RECORDED DEPOSITION OF
THOMAS WILLIAM KENNY JR., PH.D.
Zoom Recorded Videoconference
09/18/2021
9:03 a.m. Pacific Daylight Time

REPORTED BY: AMANDA GORRONO, CLR

CLR NO. 052005-01

DIGITAL EVIDENCE GROUP
1730 M Street, NW, Suite 812
Washington, D.C. 20036
(202) 232-0646

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| Masimo Ex. 2027 Apple v. Masimo IPR2021-00193 |
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1 correct?

2 A. That's correct.

3 Q. The indication in this figure,
4 "Toward the center," does that indicate the
5 redirection that leads to the detector capturing
6 light that otherwise would have been missed --

7 MR. SMITH: Objection; form.

8 Q. -- for a particular ray?

9 MR. SMITH: Same objection.

10 A. So just again, reading from
11 Paragraph 42, the "lens' ability to direct light
12 'toward the center' would allow the detector to
13 capture light that would otherwise have been missed
14 by the detectors, regardless of their location within
15 the sensor device."

16 Q. So there, there is some light that
17 would have been captured by the detectors that is
18 redirected and no longer hits the detectors; is that
19 correct?

20 MR. SMITH: Objection; form.

21 A. So of all of the photons scattered
22 backwards from all of these sites --

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1 Q. Correct.

2 A. -- and interacting with this curved
3 optical surface that we're calling the lens, some of
4 those rays are diff- -- sorry -- refracted in a way
5 that directs them toward the detectors which
6 otherwise might have missed, and there would be some
7 other rays that would have hit the detectors that are
8 refracted away from the detectors; that's correct.

9 Q. So in your analysis, did you
10 determine the relative amount of light that is
11 refracted towards the detectors that would otherwise
12 have been missed and compare it to the amount of
13 light originally going to the detector that is now
14 refracted away and misses the detector, with the
15 presence of the convex surface?

16 MR. SMITH: Objection; form.

17 A. In order to perform such an analysis,
18 I would need to know a full set of detailed
19 dimensions and shapes of the objects that would be
20 involved in that final design. So there was no such
21 detailed calculation presented for this cartoon
22 representation of the combination of elements from

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1 the references.

2 What I've stated throughout the
3 earlier Declaration and throughout the earlier
4 deposition is that a person of ordinary skill in the
5 art would understand how to take advantage of the
6 detector locations and the shape of this convex
7 surface so as to obtain an improvement in the amount
8 of light arriving at the detectors.

9 Q. The improvement in the light arriving
10 at the detectors depends on the dimensions and shapes
11 of the objects in the final design; is that correct?

12 MR. SMITH: Objection; form.

13 A. Yes, yes.

14 Q. And in this Declaration, there was no
15 detailed calculation presented for dimensions and
16 shapes that establish that relatively more light
17 reaches the detectors for a convex surface than for a
18 flat or no surface; is that correct?

19 MR. SMITH: Objection; form.

20 A. So we could read from Paragraph 44,
21 "As I made clear during my deposition," and following
22 that is a quote, I think, from the transcript of the

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1 deposition, "'The convex shape [of Inokawa's lens]
2 allows light that might have been just specularly
3 reflected off of a flat plate to be captured and
4 refracted inwards. And in the region where there's
5 curvature, it allows the light to be concentrated,
6 and in this case, roughly speaking, in the
7 neighborhood of the detectors and inwards.'" That is,
8 that the addition of a convex lens allows the
9 detectors to capture some of the reflected light
10 that...would have missed them completely, and to
11 provide some concentration of the light towards the
12 location of the detectors."

13 And again, as I explained in the
14 deposition and, and since then in these Declarations,
15 it's within the skill of one of ordinary skill in the
16 art to appreciate how to arrange the position of the
17 detectors and to arrange the shape of the lens so as
18 to obtain some benefit as described here.

19 Q. Determining whether there is a
20 benefit as described in your Declaration, would have
21 required detailed calculations for dimensions, for
22 particular dimensions and shapes of that lens and

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1 Q. I don't think that that reference, I,
2 I may be wrong, but I don't think that reference was
3 part of these proceedings, but I want to direct you
4 to part of Mendelson 1988 which I think you've cited
5 in, in these proceedings and maybe all of the
6 proceedings we've talked about today -- we're going
7 to talk about today, okay?

8 A. Uh-huh.

9 Q. Page 2 of the reference in the
10 left-hand column?

11 A. Uh-huh.

12 Q. Final paragraph in that column?

13 A. Uh-huh.

14 Q. "The intensity of the backscattered
15 light decreases," do you see that sentence?

16 A. Yes.

17 Q. So for a sensor with a central
18 emitter and peripheral detectors, the intensity of
19 the light decreases with the square of the distance;
20 is that correct?

21 A. That's what this reference says.

22 Q. And is that your understanding

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1 generally of physiological sensors that use a central
2 emitter and peripheral detectors?

3 A. I think there's other references from
4 the same authors that use the word "exponential
5 decrease or rapid decrease." And the data I remember
6 seeing is, I think, more or less consistent with all
7 of those descriptions without precisely fitting to a
8 particular analytic dependance between distance and
9 signal. So I think the general understanding that
10 all of these references would agree with is that
11 there is a decrease in the light as you move away
12 from the location of the emitter towards the
13 perimeter of the sensor.

14 Q. The decrease in the backscattered
15 light, when you -- based upon this disclosure, when
16 you go from 1 millimeter to 2 millimeters, the
17 intensity will be 25 percent of what it was 1 to 2;
18 is that, is that correct? Am I understanding that
19 correct? If you double --

20 MR. SMITH: Objection; form.

21 Q. -- if you double your distance?

22 MR. SMITH: Objection; form.

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1 BY MR. HELM:

2 Q. Dr. Kenny, before the break, we were
3 talking about Mendelson 1988. I want to go back to
4 the disclosure about the intensity of the light -- of
5 the backscattered light decreases in proportion --
6 direct proportion of the square of the distance.
7 That is Page 2 of Mendelson 1988, bottom of the first
8 column on the left.

9 A. That's -- yes.

10 Q. So based on that disclosure, if the
11 intensity of the light decreases with the square of
12 the distance, doubling the distance results in a
13 4-fold decrease in the amount of light; is that
14 correct?

15 MR. SMITH: Objection; form.

16 A. If we're considering exactly the same
17 detector just repositioned a factor or two further
18 away, then if as stated, it's -- the light decreases
19 in proportional of the square of the distance, then
20 that displacement by a factor of two in distance
21 would correspond to a factor of four reduction in the
22 signal for that detector.

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1 detectors in, for example, Figure 14E.

2 Q. The description indicates that the
3 light is focused or substantially focused, correct?

4 A. That's correct.

5 Q. Figure 14 is not intended to show
6 solely light that's focused on a single detector,
7 correct?

8 MR. SMITH: Objection; argumentative.

9 A. All I can say is what it shows, so
10 Figure 14B shows rays of light coming in, being
11 refracted by the convex protruding surface and
12 converging at least schematically at a single point
13 on the detector. I think one of ordinary skill would
14 understand there's going to be some perhaps
15 imperfections in some of the details of this
16 structure that might lead to something less than an
17 absolute precise focal point. But it's clear from
18 what I see here, the intent is to gather collimated
19 light and, and concentrate it at the location and
20 maybe even within the area of the detectors to
21 guarantee maximum detection.

22 Q. Figure 14B is a cartoon, correct?

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1 A. I think so, just like all the others.

2 MR. SMITH: Hold on. Objection:

3 Form.

4 Q. Figure 14B is not intended to
5 represent all possibilities for incoming light,
6 correct?

7 MR. SMITH: Objection; form.

8 A. I'm not sure what the illustrator had
9 in mind here, but they made a choice to show the
10 light rays from the emitters as entirely consisting
11 of a series of parallel rays coming in. They could
12 easily have had made those sets of rays somewhat less
13 organized, if they had chosen to do so, but this
14 figure shows what it shows. I think one of ordinary
15 skill in the art would look at this and say you have
16 collimated light coming into a cylindrical lens and
17 being focused almost precisely to a single point.

18 The actual detectors have a finite
19 size and shape and I think there's some other
20 language that we can go look at it if you want, but
21 there's some discussion about the vertical
22 positioning of this convex protrusion relative to the

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1 Paragraph 22 and the illustrations there, show how
2 one of ordinary skill in the art might design a
3 convex surface so as to improve the light gathering
4 around the perimeter from a diffuse source and, and
5 carry all of that out in the context of the
6 combination of Inokawa and Ohsaki or Aizawa.

7 Q. Would a skilled artisan use a
8 different convex surface design to increase light
9 gathering at the center of a sensor for a diffuse
10 source?

11 MR. SMITH: Objection; vague.

12 A. So I think around Paragraph 22, I
13 provide an illustration of a convex surface that has
14 greater curvature at the perimeter than it has in the
15 center and that the effect of that curvature on the
16 orientation of those orthogonal axes is one that
17 would allow an increase in the number of rays coming
18 in from a diffuse source to arrive at the location of
19 the detector.

20 Q. Inokawa's detector involves diffuse
21 light, correct?

22 MR. SMITH: Objection; vague.

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1 A. Yes, it's a reflective pulse
2 oximeter. I think one of ordinary skill would
3 understand that the illustrations in Inokawa are
4 describing diffuse light source that's providing
5 light back to the detectors.

6 Q. If Inokawa's lens is beneficial
7 whether the detectors are in the middle or on the
8 periphery, why did you change its shape when you
9 applied it to Aizawa?

10 MR. SMITH: Objection;
11 mischaracterizes prior testimony.

12 A. So, again, the lens of Inokawa is
13 maybe conceptually described in only a few sentences
14 and the only characteristic that we're given of the
15 lens design is it improves the light gathering of the
16 LED, which is, I think, a way of saying that it
17 improves the overall efficiency of the system, but we
18 are not given a particular shape or a thickness or a
19 material or anything else that would allow me to make
20 a comparative statement between two designs.

21 I'm just providing in Figure 22,
22 which is a sort of cropped and expanded segment of

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1 figures provided in my earlier Declaration, showing
2 the arrangement of a curvature that I think one of
3 ordinary skill in the art would understand to be
4 beneficial if the objective is to gather more light
5 from a diffuse light source and bring it to the
6 detecting elements.

7 Q. The figure you provided, the cropped
8 figure in your Declaration, is a different shape from
9 the cover depicted in Inokawa, correct?

10 MR. SMITH: Objection; argumentative.

11 A. So I didn't perform a detailed
12 analysis of the shape depicted in the cartoon
13 illustration in Inokawa, and I didn't copy and paste
14 that particular shape into the combination that I
15 think one of ordinary skill would arrive at. I
16 believe one of ordinary skill in the art would
17 understand that Inokawa is teaching that a lens-like
18 shape can be used to improve the light gathering
19 ability of the LED and that when attempting to
20 combine a lens-like shape with a particular
21 arrangement of detectors and emitters, one would
22 consider a specific convex shape that would be likely

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1 flawed mis- -- that's a flawed understanding of the
2 physics of the system. The light ray shown in
3 Inokawa can exist regardless of the -- whether the
4 detector and the emitter are in the center or the
5 edge. If you swap those positions, the same exact
6 light path is possible.

7 Q. Is it true that a different lens
8 design will benefit Inokawa's depicted configuration
9 of peripheral emitters and a central detector as
10 compared to Aizawa's configuration of a central
11 emitter and peripheral detectors?

12 MR. SMITH: Objection; form.

13 Q. That is true, correct?

14 MR. SMITH: Sorry, objection; form.

15 A. So the lens design in Inokawa is not
16 actually a lens design. It's a -- just a cartoon
17 showing the lens. One -- I think if one was building
18 Inokawa's device with the peripheral emitters and the
19 central detector, one would do some work to
20 understand the, the full array of light paths that
21 are likely to be present in this case and not just
22 the two illustrated arrows in the drawing. One would

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1 then chose a particular shape which might depart from
2 the cartoon shape in order to arrive at a beneficial
3 arrangement for a particular arrangement of detectors
4 and emitters.

5 All of this would also depend on the
6 size of the detectors, the number and locations of
7 the emitters and vice versa. I think the general
8 overarching statement is that one would tailor the
9 design of the lens to correspond to the features of
10 the specific system involved and that if you simply
11 swap emitter detector positions, there might be some
12 benefits to that, but the main point of all of this
13 discussion is that the light rays shown in Inokawa
14 can go either direction.

15 Q. Did you do any ray tracing on your
16 combination implementing a convex surface on top of
17 Aizawa to determine whether your convex surface
18 actually focused more light on the peripheral
19 detectors?

20 MR. SMITH: Objection; form.

21 A. So I did not perform a detailed
22 retrace analysis of the diffuse light source applied

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Poeze, et al.
U.S. Patent No.: 10,376,190 Attorney Docket No.: 50095-0010IP1
Issue Date: August 13, 2019
Appl. Serial No.: 16/409,304
Filing Date: May 10, 2019
Title: MULTI-STREAM DATA COLLECTION SYSTEM FOR NONIN-
VASIVE MEASUREMENT OF BLOOD CONSTITUENTS

Mail Stop Patent Board

Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

**PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT
NO. 10,376,190 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42**

APPLE-1006, FIG. 1(b) (modified); APPLE-1003, ¶104.

Claim 11

[11]: “The noninvasive optical physiological measurement device of claim 10, wherein the light permeable cover is configured to act as a tissue shaper and conform tissue of the user to at least a portion of an external surface shape of the light permeable cover when the noninvasive optical physiological measurement device is worn by the user.”

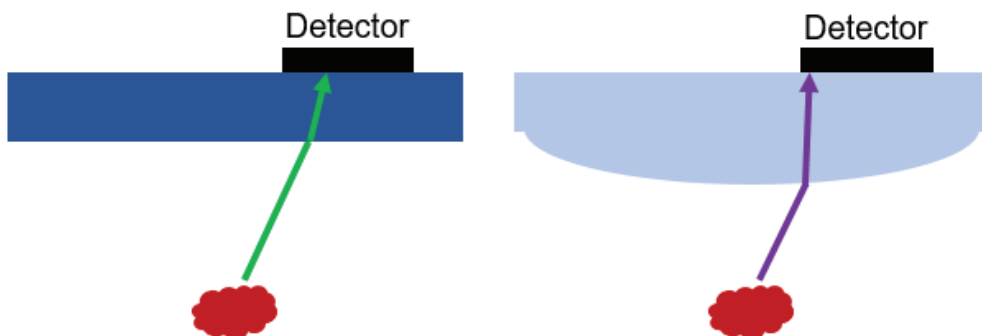
Aizawa-Inokawa renders obvious [11]. *Supra* Ground-1A [10]; APPLE-1003, ¶105. As explained for [10], the light permeable cover of Aizawa-Inokawa deforms the tissue around the lens/protrusion when pressed against the wrist of the user. APPLE-1003, ¶105. Thus, the light permeable cover shapes the tissue around its external surface when the device is worn. *Id.*

Claim 12

[12]: “The noninvasive optical physiological measurement device of claim 11, wherein the light permeable cover is configured to reduce a mean path length of light traveling to the at least four detectors.”

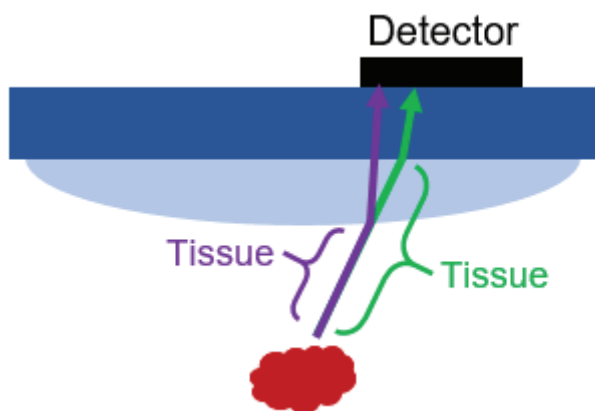
A POSITA would have recognized that such feature is rendered obvious by Aizawa-Inokawa. APPLE-1003, ¶106. For example, the lens/protrusion of Inokawa, which is used to modify Aizawa as explained in Section III.A.3, serves a condensing function and thus, as with any other lens, refracts light passing through it. APPLE-1008, [0015], [0058]; APPLE-1003, ¶107. Thus, referring to the drawing below which compares the length of non-refracted light (*i.e.*, without a lens, left) bouncing off an artery with that of refracted light (*i.e.*, with a lens, right),

it can be seen that the mean path length of light traveling to the at least four detectors is reduced—that is, the purple line is shorter than the green line. APPLE-1003, ¶107. This holds true for both the total length travelled as well as length travelled/attenuated through skin. *Id.*



APPLE-1003, ¶107.

Superimposing the two drawings above clearly shows the shortened path traveled by refracted light in the presence of a protrusion/lens, both within the tissue as well as for total path length:



APPLE-1003, ¶108.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE, INC.,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

Case IPR2021-00195
Patent 10,376,190

PETITIONER'S EXHIBIT LIST

EXHIBITS

| | |
|------------|---|
| APPLE-1001 | U.S. Patent No. 10,376,190 to Poeze, et al. (“the ’190 patent”) |
| APPLE-1002 | Excerpts from the Prosecution History of the ’190 patent (“the Prosecution History”) |
| APPLE-1003 | Declaration of Dr. Thomas W. Kenny |
| APPLE-1004 | Curriculum Vitae of Dr. Thomas W. Kenny |
| APPLE-1005 | <i>Masimo Corporation, et al. v. Apple Inc.</i> , Complaint, Civil Action No. 8:20-cv-00048 (C.D. Cal.) |
| APPLE-1006 | U.S. Pub. No. 2002/0188210 (“Aizawa”) |
| APPLE-1007 | JP 2006-296564 (“Inokawa”) |
| APPLE-1008 | Certified English Translation of Inokawa and Translator’s Declaration |
| APPLE-1009 | U.S. Pat. No. 7,088,040 (“Ducharme”) |
| APPLE-1010 | U.S. Pat. No. 8,177,720 (“Nanba”) |
| APPLE-1011 | RESERVED |
| APPLE-1012 | U.S. Pat. No. 6,853,304 (“Reisman”) |
| APPLE-1013 | U.S. Pub. No. 2004/0220738 (“Nissila”) |
| APPLE-1014 | U.S. Pub. No. 2001/0056243 (“Ohsaki”) |

- APPLE-1015 “Design and Evaluation of a New Reflectance Pulse Oximeter Sensor,” Y. Mendelson, et al.; Worcester Polytechnic Institute, Biomedical Engineering Program, Worcester, MA 01609; Association for the Advancement of Medical Instrumentation, vol. 22, No. 4, 1988; pp. 167-173 (“Mendelson-1988”)
- APPLE-1016 “A Wearable Reflectance Pulse Oximeter for Remote Physiological Monitoring,” Y. Mendelson, et al.; Proceedings of the 28th IEEE EMBS Annual International Conference, 2006; pp. 912-915 (“Mendelson-2006”)
- APPLE-1017 Excerpt from Merriam-Webster Dictionary
- APPLE-1018 “Acrylic: Strong, stiff, clear plastic available in a variety of brilliant colors,” available at <https://www.curbellplastics.com/Research-Solutions/Materials/Acrylic>
- APPLE-1019 U.S. Pat. No. 7,031,728 (“Beyer”)
- APPLE-1020 U.S. Pat. No. 7,092,735 (“Osann, Jr.”)
- APPLE-1021 U.S. Pat. No. 6,415,166 (“Van Hoy”)
- APPLE-1022 QuickSpecs; HP iPAQ Pocket PC h4150 Series
- APPLE-1023 U.S. Pat. App. Pub. No. 2007/0145255 (“Nishikawa”)
- APPLE-1024 “Measurement Site and Photodetector Size Considerations in Optimizing Power Consumption of a Wearable Reflectance Pulse Oximeter,” Y. Mendelson, et al.; Proceedings of the 25th IEEE EMBS Annual International Conference, 2003; pp. 3016-3019 (“Mendelson-2003”)
- APPLE-1025 U.S. Pat. No. 6,801,799 (“Mendelson-’799”)

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|--------------------|---|
| APPLE-1026 | Declaration of Jacob Munford |
| APPLE-1027 | U.S. Pub. No. 2007/0093786 (“Goldsmith”) |
| APPLE-1028 | U.S. Pub. No. 2004/0138568 (“Lo”) |
| APPLE-1029 | Wikipedia: The Free Encyclopedia, “Universal asynchronous receiver-transmitter” at https://en.wikipedia.org/wiki/Universal_asynchronous_receiver-transmitter , last accessed 08/27/2020 |
| APPLE-1030 | U.S. Pub. No. 2008/0242958 to Al-Ali et al. (“Al-Ali”) |
| APPLE-1031 to 1036 | RESERVED |
| APPLE-1037 | <i>Masimo Corporation, et al. v. Apple Inc.</i> , Second Amended Complaint, Civil Action No. 8:20-cv-00048 (C.D. Cal.) (Redacted) |
| APPLE-1038 | U.S. Patent No. 8,577,431 to Lamego et al. (“CIP Patent”) |
| APPLE-1039 | Order Re Motion to Stay in <i>Masimo Corporation et al. v. Apple Inc.</i> , Case 8:20-cv-00048-JVS-JDE, October 13, 2020 |

Filed July 27, 2022

On behalf of:

Patent Owner Masimo Corporation
By: Jarom D. Kesler (Reg. No. 57,046)
Joseph R. Re (Reg. No. 31,291)
Stephen W. Larson (Reg. No. 69,133)
Jacob L. Peterson (Reg. No. 65,096)
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614
Tel.: (949) 760-0404
Email: AppleIPR2021-0195-190@knobbe.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.

Petitioner,

v.

MASIMO CORPORATION,

Patent Owner.

IPR2021-00195
Patent 10,376,190

**PATENT OWNER'S NOTICE OF APPEAL TO
THE U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

Pursuant to 28 U.S.C. § 1295(a)(4)(A), 35 U.S.C. §§ 141(c), 142, and 319, 37 C.F.R. §§ 90.2(a) and 90.3, and Rule 4(a) of the Federal Rules of Appellate Procedure, Patent Owner Masimo Corporation (“Masimo”) hereby appeals to the United States Court of Appeals for the Federal Circuit from the Judgment – Final Written Decision (Paper 32) entered on May 25, 2022 (Attachment A) and from all underlying orders, decisions, rulings, and opinions that are adverse to Masimo related thereto and included therein, including those within the Decision Granting Institution of *Inter Partes* Review, entered June 3, 2021 (Paper 7). Masimo appeals the Patent Trial and Appeal Board’s determination that claims 1-14 and 16-30 of U.S. Patent 10,376,190 are unpatentable, and all other findings and determinations, including but not limited to claim construction, as well as all other issues decided adverse to Masimo’s position or as to which Masimo is dissatisfied in IPR2021-00195 involving Patent 10,376,190.

Masimo is concurrently providing true and correct copies of this Notice of Appeal, along with the required fees, to the Director of the United States Patent and Trademark Office and the Clerk of the United States Court of Appeals for the Federal Circuit.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: July 27, 2022

By: /Jarom Kesler/

Jarom D. Kesler (Reg. No. 57,046)

Joseph R. Re (Reg. No. 31,291)

Stephen W. Larson (Reg. No. 69,133)

Jacob L. Peterson (Reg. No. 65,096)

Attorneys for Patent Owner

Masimo Corporation

Doc Code: TRACK1.REQ

Document Description: TrackOne Request

PTO/AIA/424 (04-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

| | | | |
|-----------------------|---|---|----------|
| First Named Inventor: | Jeroen Poeze | Nonprovisional Application Number (if known): | Herewith |
| Title of Invention: | MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS | | |

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently \$0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.
2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.
3. The applicable box is checked below:

I. ☒ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

- i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.
---OR---
- (b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.
- ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, or the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

- i. A request for continued examination has been filed with, or prior to, this form.
- ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
- iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
- iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
- v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

| | |
|--|---|
| Signature /Scott Cromar/ | Date 2019-05-10 |
| Name (Print/Typed) Scott Cromar | Practitioner Registration Number 65066 |
| <p>Note: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.*</p> | |
| <p><input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.</p> | |

Application/Control Number: 16/409,304
Art Unit: 3791

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DETAILED ACTION

1. Claims 2-31 are allowed.
2. The following is an examiner's statement of reasons for allowance: The following is an examiner's statement of reasons for allowance: The Terminal Disclaimers of USPNs 8,437,825; 10,258,265; 10,292,628; and 10,299,708 and copending application Nos.16/409,515 are approved on 06/12/2019 to resolve the double patenting issues. Wong et al. (USPN 5,601,079 – applicant cited) teaches a noninvasive optical physiological measurement device (Figs. 4-8 and associated descriptions) comprises a plurality of emitters of different wavelengths; a housing having a surface and a circular wall protruding from the surface; a plurality of detectors arranged on the surface and spaced apart from each other (see Figs. 4-8 and associated descriptions). Schulz et al. (USPN 7,341,559 – applicant cited) teaches an pulse oximeter (Fig. 19B and associated descriptions) comprises a plurality of emitters of different wavelengths; a detector; a housing having a surface and a circular wall protruding from the surface; a light permeable cover arranged above at least a portion of the housing, the light permeable cover comprising a protrusion arranged to cover the detector (see Fig. 19B and associated descriptions). Chaiken et al. (USPN 6,223,063 – applicant cited) teaches an optical physiological measurement device (Figs. 1-3 and associated descriptions) comprises a plurality of emitters of different wavelengths; four detectors arranged on the surface and spaced apart from each other; a plurality of lenses each covers/ in optical communication with a respective detector (see Figs. 1-3 and associated descriptions). However, the prior art of record does not teach or suggest “*a housing having a surface*

Application/Control Number: 16/409,304
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and a circular raised edge extending from the surface; at least four detectors arranged on the surface and spaced apart from each other; a light permeable cover arranged above at least a portion of the housing, the light permeable cover comprising a protrusion arranged to cover the at least four detectors” or “a circular housing comprising a surface and a wall protruding from the surface; at least four detectors arranged on the surface, wherein a first detector is arranged spaced apart from a second detector, and a third detector arranged spaced apart from a fourth detector; and a cover of the circular housing comprising a lens portion, the lens portion comprising a protrusion in optical communication with the at least four detectors” in combination with the other claimed elements/ steps.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHU CHUAN LIU whose telephone number is (571)270-5507. The examiner can normally be reached on M-Th (8am-6pm).

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Poeze et al.
U.S. Patent No.: 10,376,190 Attorney Docket No.: 50095-00010IP1
Issue Date: August 13, 2019
Appl. Serial No.: 16/409,304
Filing Date: May 10, 2019
Title: MULTI-STREAM DATA COLLECTION SYSTEM FOR
NONINVASIVE MEASUREMENT OF BLOOD
CONSTITUENTS

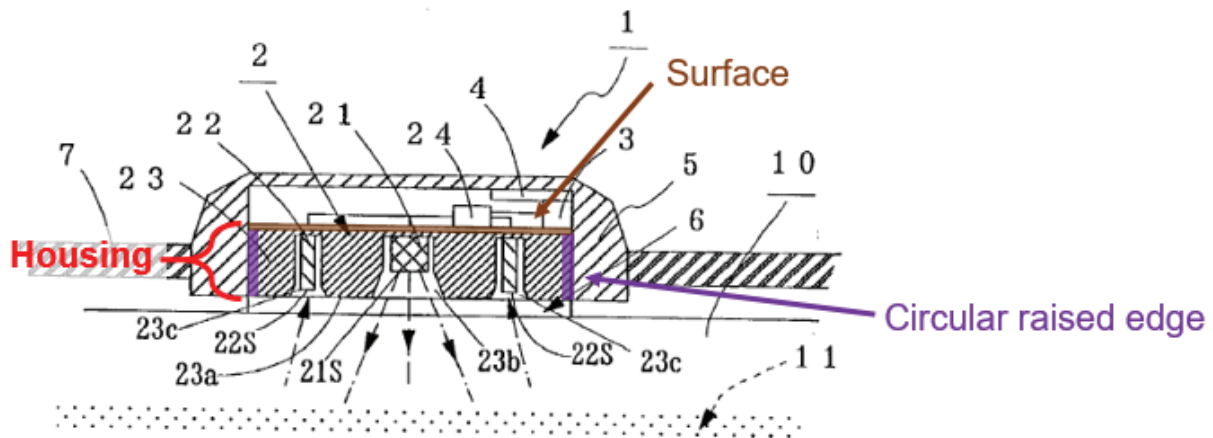
DECLARATION OF DR. THOMAS W. KENNY

Declaration

I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable under Section 1001 of Title 18 of the United States Code.

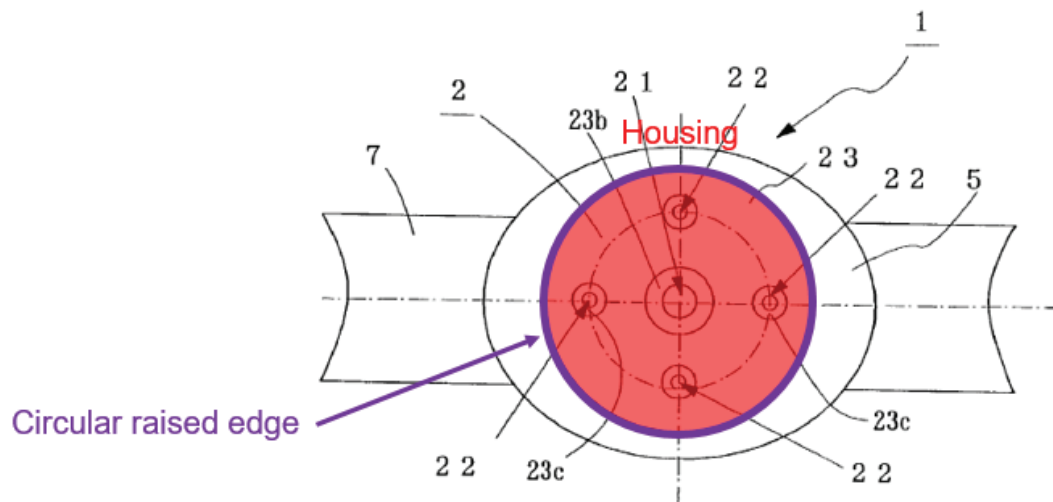
By:  _____

Thomas W. Kenny, Ph.D.



APPLE-1006, FIG. 1(b)

76. Thus, the holder and the flat surface together provide the housing element as required by this claim. Moreover, referring to FIG. 1(b) above and FIG. (1a) below, the outer periphery of Aizawa's holder 23 provides a circular raised edge (colored purple) that protrudes from the surface.

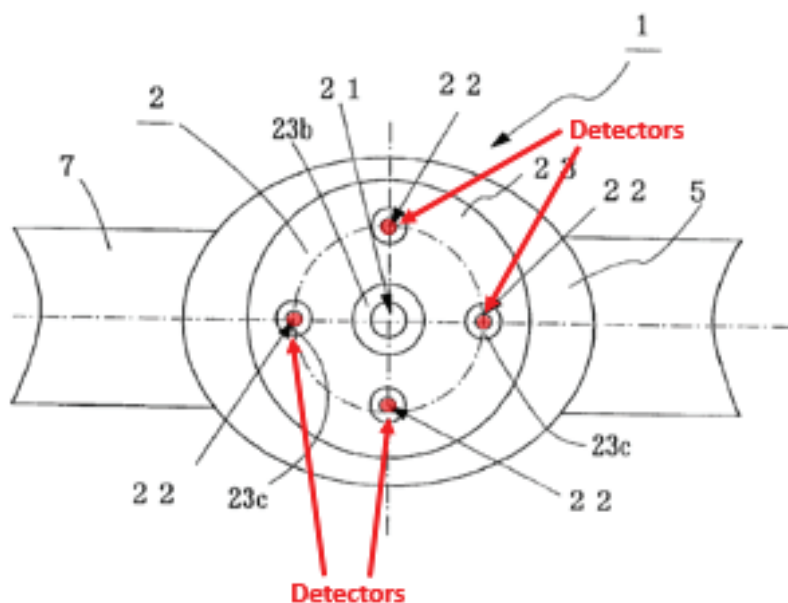


Apple-1006, FIG. 1(a)

[1c] at least four detectors arranged on the surface and spaced apart from each other, the at least four detectors configured to output one or more signals

responsive to light from the one or more light emitters attenuated by body tissue, the one or more signals indicative of a physiological parameter of the wearer; and

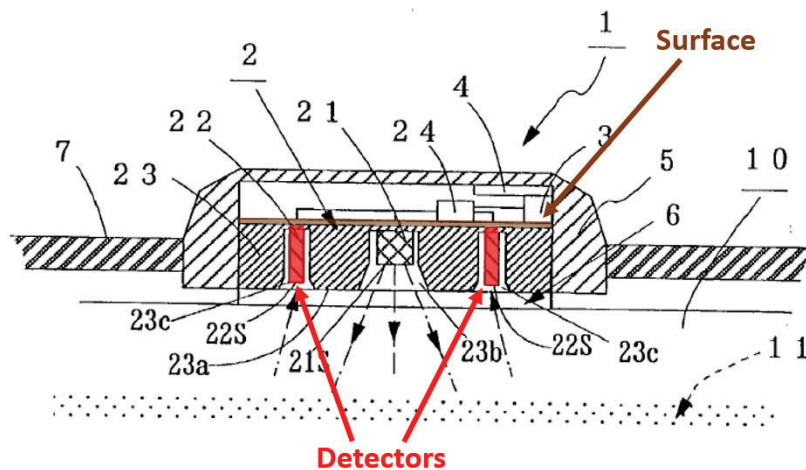
77. As illustrated below, Aizawa teaches “four photodetectors 22 disposed around the light emitting diode 21 symmetrically on a circle concentric to the light emitting diode 21.” APPLE-1006, [0029], [0024], [0032]. These four detectors are, as seen below, spaced apart from each other by being arranged symmetrically in a circular pattern. *Id.*



APPLE-1006, FIG. 1(a)

78. Moreover, these four detectors are arranged *on the surface* of the housing as identified above for element [1c]. In particular, as shown below, the detectors are positioned within the holder 23 and are further connected, through the surface (shown in brown), to a drive circuit 24 on the other side of the housing. *Id.*,

[0023]. A POSITA would have understood that circuit 24 and other wires/electronics are connected to the detectors *through* the surface, and, therefore, the surface provides physical support to the detectors. *Id.* Indeed, it is well-known to mount electronic components, such as photodiodes and LEDs, to a flat surface such as a ceramic substrate or a circuit board to provide both mechanical and electrical coupling. [0017], FIG. 2; APPLE-1015, 168, FIG. 2B.



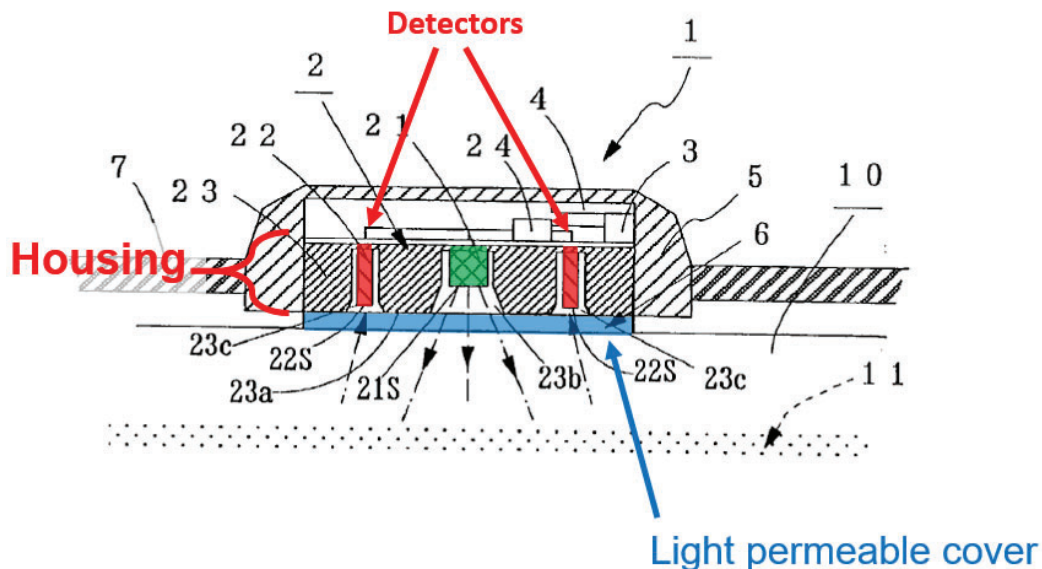
APPLE-1006, FIG. 1(b)

79. Regarding the signals that are output by Aizawa's detectors, Aizawa's photodetectors 22 are designed to detect light that is "reflected by a red corpuscle running through the artery 11 of the wrist 10 ... so as to detect a pulse wave." APPLE-1006, [0027]. Aizawa subsequently "detect[s] a pulse wave by amplifying the outputs of the photodetectors 22." *Id.*, [0023]. For example, Aizawa's detectors output "waveform of a pulse wave," and this output is amplified and

converted into a digital signal to compute the pulse rate. *Id.*, [0028]. Thus, the detectors of Aizawa “output one or more signals responsive to light from the one or more light emitters attenuated by body tissue” and this signal is further “indicative of a physiological parameter of the wearer.”

[1d] a light permeable cover arranged above at least a portion of the housing, the light permeable cover comprising a protrusion arranged to cover the at least four detectors.

80. As explained above and shown below, Aizawa teaches a light permeable cover in the form of an acrylic transparent plate 6 (colored blue) that is mounted at the detection face 23a over at least a portion of the housing to cover the at least four detectors (colored red). APPLE-1006, [0023].

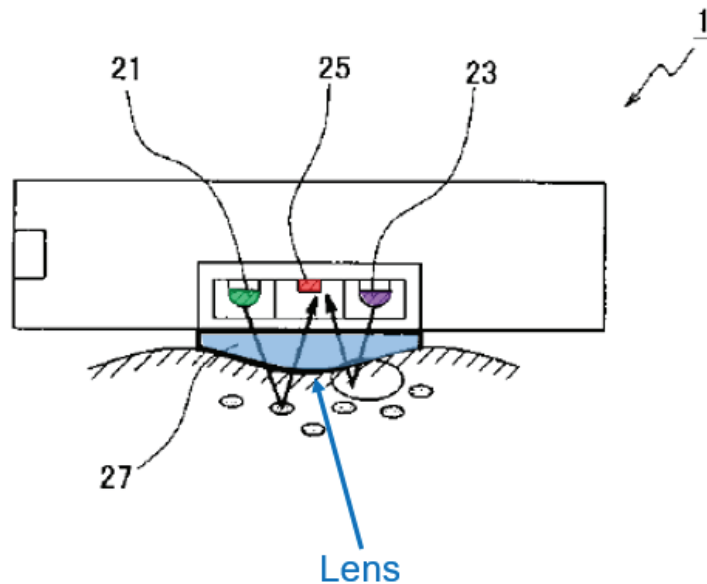


APPLE-1006, FIG. 1(b) (annotated), [0023]

81. However, the acrylic plate of Aizawa is flat and is not described as including a protrusion.

82. Additionally, a POSITA would have been motivated and known how to modify the flat shape of Aizawa's acrylic plate to achieve a particular, desired objective. For example, Aizawa teaches that its light permeable cover (*i.e.*, acrylic transparent plate) helps improve "detection efficiency," but does not otherwise provide more details about how, for instance based on its shape or material properties, such an effect may be achieved. APPLE-1006, [0030]. But a POSITA would have readily recognized that the shape of Aizawa's plate could be modified based on well-known techniques to help achieve Aizawa's objective of improving detection efficiency. APPLE-1006, [0013], [0030], [0032]; APPLE-1009 at 3:46-51.

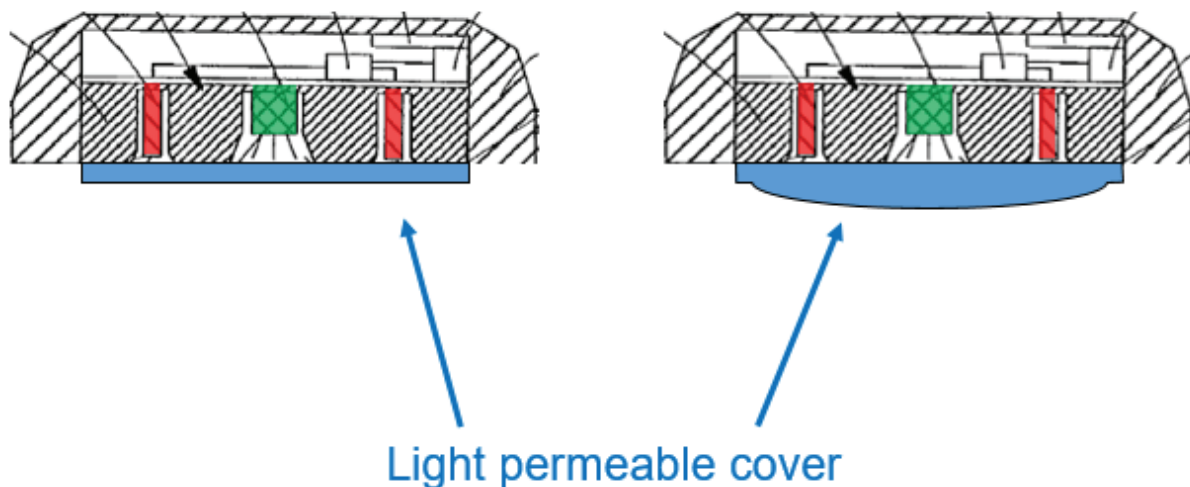
83. As one example, a POSITA would have been able to look to Inokawa to enhance light collection efficiency, in particular by modifying the light permeable cover of Aizawa to include a convex protrusion that acts as a lens, as per Inokawa. APPLE-1008, FIG. 2. As illustrated below, Inokawa teaches a side lens 27 (colored blue) that is positioned between a pulse sensor and the user's skin. *Id.*



APPLE-1008, FIG. 2

84. Inokawa teaches that the “lens makes it possible to increase the light-gathering ability of the LED.” *Id.*, [0015]. Thus, a POSITA would have sought to incorporate a convex, lens-like shape as in Inokawa into Aizawa’s acrylic plate to thereby increase light collection efficiency, in turn leading to more reliable pulse wave detection. The lens of Inokawa can provide this benefit by refracting and concentrating the light coming in through Aizawa’s acrylic plate after being reflected by the blood. Incidentally, because the path of light is reversible, the light collection function of Inokawa’s lens would work the same way regardless of whether light is emitted toward the center (and detected by a centrally located photodiode) or emitted away from the center (and detected by a peripherally located photodiode).

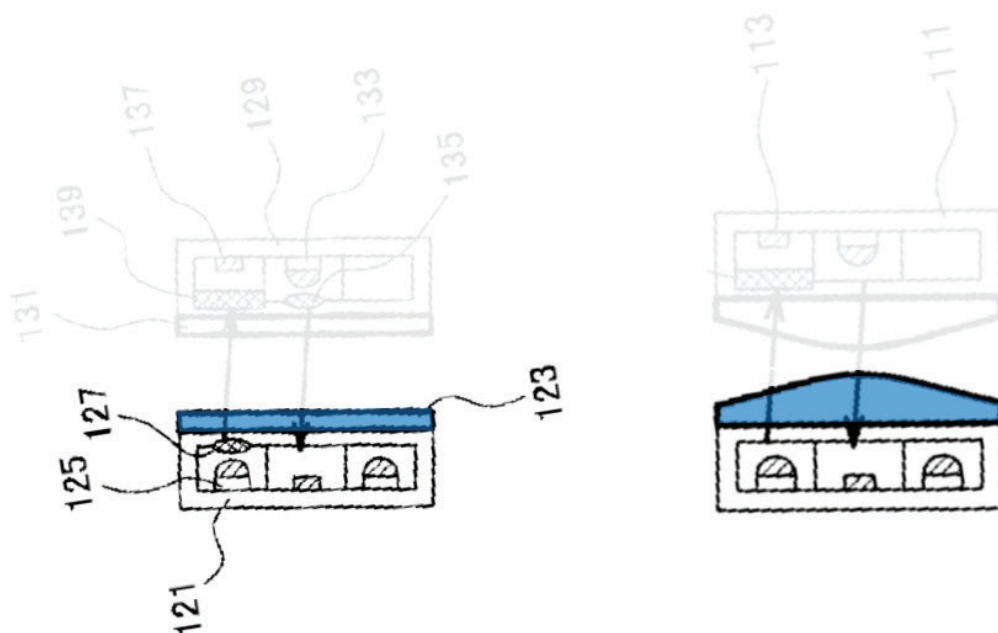
85. In more detail, a POSITA would have found it obvious to combine the teachings of Aizawa and Inokawa such that the flat cover (left) of Aizawa is modified to include a lens/protrusion (right) as per Inokawa in order to “increase the light-gathering ability.” APPLE-1008, [0015]. Indeed, by positioning a lens above the optical components of Aizawa, as shown below, the modified cover will allow more light to be gathered and refracted toward the light receiving cavities of Aizawa, thereby further increasing the light-gathering ability of Aizawa beyond what is achieved through the tapered cavities. APPLE-1006, [0012], [0024]. Here, a POSITA would have found it obvious to make the protrusion portion of the LPC—namely the lens-shaped light-gathering portion—to ensure that the light-concentration effect achieved by the lens impacts all of the detectors.



APPLE-1006, FIG. 1(b)

86. A POSITA would have further understood *how* to incorporate the shape of Inokawa’s cover into Aizawa’s cover, and further would have expected such a

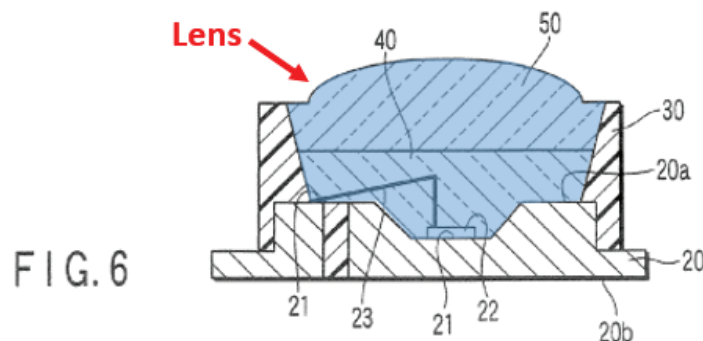
modification to succeed given the high degree of overlap between the two references. For example, as shown below, Inokawa teaches that its light permeable cover can be flat (left) so that “the surface is less prone to scratches,” or alternatively be in the form of a lens (right) to “increase the light-gathering ability of the LED.” APPLE-1008, [0015], [0016]. That is, depending on the desired objective of the user (*e.g.*, less scratches or improved light-gathering), the shape of the cover can be readily modified. Moreover, by choosing the material of the protrusion to be scratch-resistant, such as glass, it would have been obvious for a POSITA to achieve both benefits at once.



APPLE-1008, FIG. 17 (left), FIG. 16 (right)

87. A POSITA would have further recognized that the acrylic material used to make Aizawa’s acrylic transparent plate 6 can be easily formed to include a lens.

See APPLE-1009 at 3:46-51, FIG. 1; APPLE-1023, FIG. 6, [0022], [0032], [0035]. Indeed, many prior art references of this period, such as Nishikawa (shown below) demonstrate exactly how such a lens shape may be incorporated into a molded cover. APPLE-1023, FIG. 6, [0022], [0032], [0035]. In other words, a POSITA would have known that acrylic is a transparent material that can be readily transformed into various shapes, including a lens shape, as needed due to its easy molding properties. *Id.* Thus, a POSITA preferring improved light collection efficiency over reduced susceptibility to scratches could have been able to easily modify Aizawa's cover to have a lens shape as per Inokawa. *Id.* Indeed, only a routine knowledge of sensor design and assembly, which were well within the skill of a POSITA, would be required to perform such modifications. Thus, to achieve the goal of improving light collection efficiency, which both Aizawa and Inokawa share, a POSITA would have been able to, with a reasonable expectation of success, modify Aizawa's light permeable cover to have a lens shape as taught by Inokawa.



APPLE-1023, FIG. 6

In this way, the lens/protrusion acts as a tissue shaper that helps conform the tissue of the user to an external surface of the lens/protrusion when the device is worn by the user. *Id.* As explained for [10], this happens because a protruded surface that is more rigid than the skin is being pressed into the skin and, accordingly, the less rigid skin will at least partially deform to conform to the rigid protrusion. *Id.*

K. Claim 12

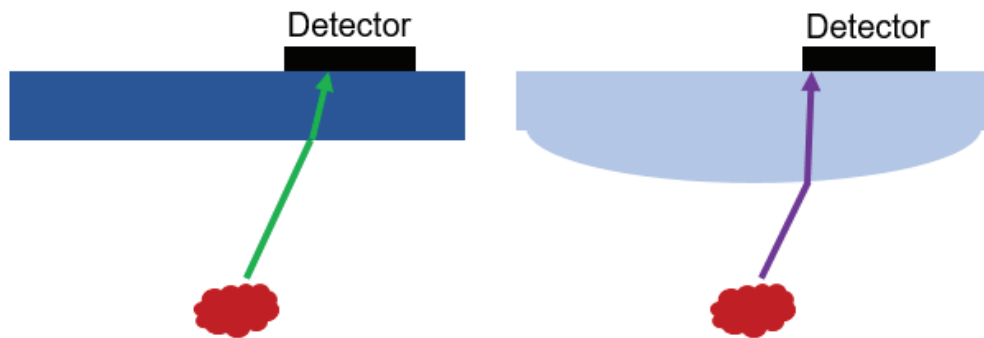
[12] The noninvasive optical physiological measurement device of claim 11, wherein the light permeable cover is configured to reduce a mean path length of light traveling to the at least four detectors.

106. Regarding the reduction of mean path length, the '190 patent mentions, in the context of a transmittance-type device, that using a protruded cover to deform the skin can cause “the mean optical path length from the emitters to the detectors can be reduced and the accuracy of blood analyte measurement can increase.”

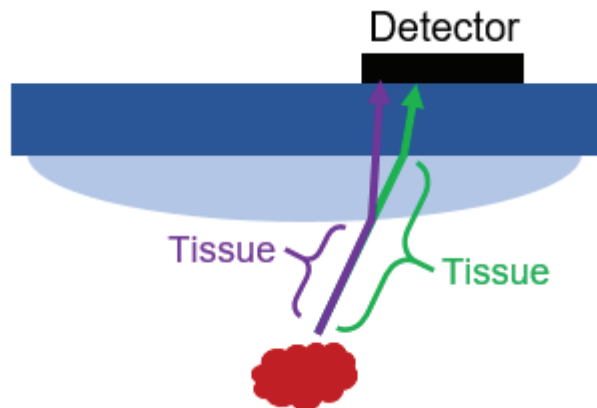
APPLE-1001, 20:25-20, FIG. 5. Although the '190 patent is silent regarding how such path reduction would apply in a reflectance-type sensor, a POSITA still would have recognized that an analogous effect can be achieved the Aizawa-Inokawa combination.

107. In more detail, I noted above for [1d] how the lens/protrusion of Inokawa, which is used to modify Aizawa's cover, provides a condensing function by refracting the light passing through it. APPLE-1008, [0015], [0058]. As demonstrated through my drawings below, where the left figure shows the length

of non-refracted light and the right figure shows the length of refracted light, such refraction of the incoming reflected light can shorten the path of the light before it reaches the detector. This is because the incoming light is “condensed” toward the center. APPLE-1008, [0015], [0058]. Thus, as demonstrated by the drawings below, both the total length of travel as well as the length through the tissue can be reduced.



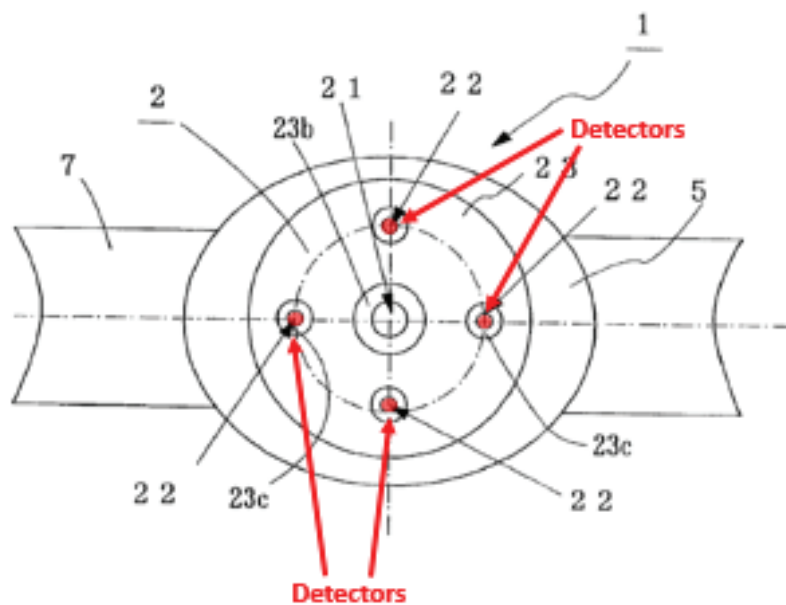
108. Laying these two drawings on top of each other, as shown below, the shortened path length within the tissue for the purple (refracted) line can be clearly seen compared to the path length within the tissue of the green (non-refracted) line. The shortened *total* path length of the purple line compared to the green line can also be seen. Accordingly, the Aizawa-Inokawa combination, through its use of a condensing lens between the tissue and the detectors, serves to reduce a mean path length of light traveling to the at least four detectors



L. Claim 13

[13] The noninvasive optical physiological measurement device of claim 11, wherein the at least four detectors are evenly spaced from one another.

109. As explained above with respect to [c], Aizawa teaches at least four detectors. APPLE-1006, [0029], [0024], [0032], FIG. 1(a). Further, as shown below, the four detectors are evenly spaced from one another. *Id.*



APPLE-1006, FIG. 1(a)

X. Claim 29

[29] The noninvasive optical physiological measurement device of claim 27, wherein the first, second, third and fourth detectors form a cross pattern about the central axis.

127. For reasons I discussed above in ¶ 116 with respect to element [21], herein incorporated by reference, this limitation is rendered obvious by the Aizawa-Inokawa combination. APPLE-1006, [0029], [0024], [0032], FIG. 1(a).

IX. GROUND 1B –Claims 1-14, 16, 17, 19-23, and 26-29 Are Rendered Obvious by Aizawa in view of Inokawa and Ohsaki

A. Claims 1-14, 16, 17, 19-23, and 26-29

[1d] a light permeable cover arranged above at least a portion of the housing, the light permeable cover comprising a protrusion arranged to cover the at least four detectors.

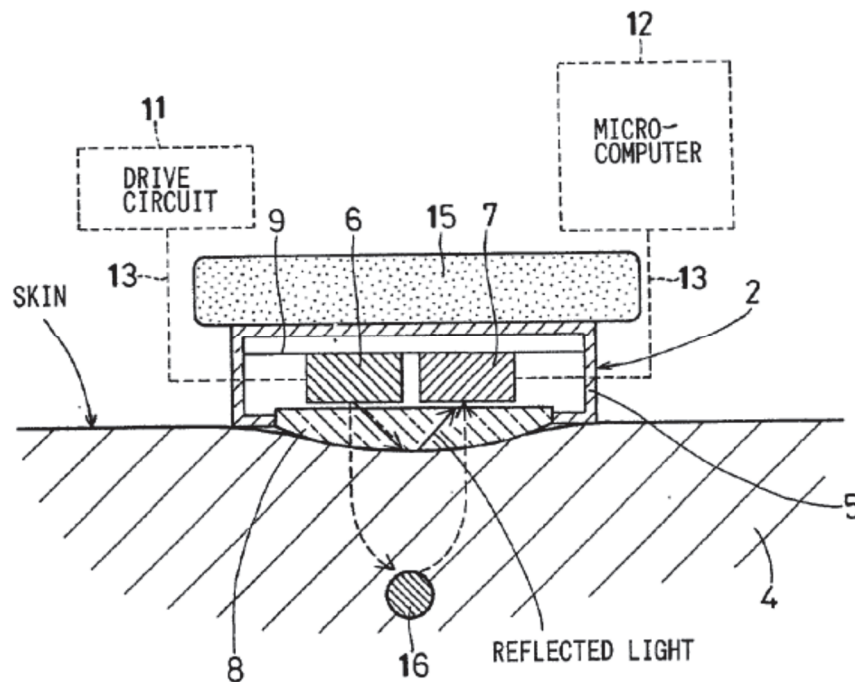
128. As I explained above in ¶¶ 80-87 with respect to element [1d], a POSITA would have been motivated to incorporate a lens-like protrusion of Inokawa into the cover of Aizawa to increase the light collection efficiency.

129. Ohsaki (APPLE-1014), which I briefly described above ¶¶ 64-65 provides an alternative/additional rationale for why a POSITA would have modified the flat shape of Aizawa’s acrylic plate into a “light permeable cover comprising a protrusion” as per element [1d].

130. Among other things, Ohsaki teaches that adding a convex surface to its translucent board 8 (*i.e.*, light permeable cover) can help prevent the device from

slipping on the tissue of the wearer compared to using a flat cover without such a protrusion. APPLE-1014, [0025].

FIG. 2



APPLE-1014, FIG. 2

131. Minimizing slippage between a user-worn sensor device and the tissue of the user was indeed a well-known objective in such devices. For example, Aizawa teaches using its acrylic transparent plate 6 (*i.e.*, light permeable cover) to improve “adhesion between the wrist 10 and the pulse rate detector 11.” APPLE-1006, [0026], [0030]. While Aizawa doesn’t discuss whether the shape of its acrylic plate could be modified to achieve this objective, a POSITA in possession of both Aizawa and Ohsaki would have recognized that Ohsaki’s addition of a convex protrusion to its light permeable cover could be similarly implemented in Aizawa’s

device to help achieve the two references' shared goal of minimizing slippage. *Id.*

In other words, a POSITA seeking to achieve improved adhesion between the detector and the skin, as expressly recognized in Aizawa, would have been motivated and readily able to modify Aizawa's acrylic plate to have a convex shape as in Ohsaki. This would have allowed Aizawa's sensor device to remain better adhered to the skin and thereby increase its light-collecting efficiency.

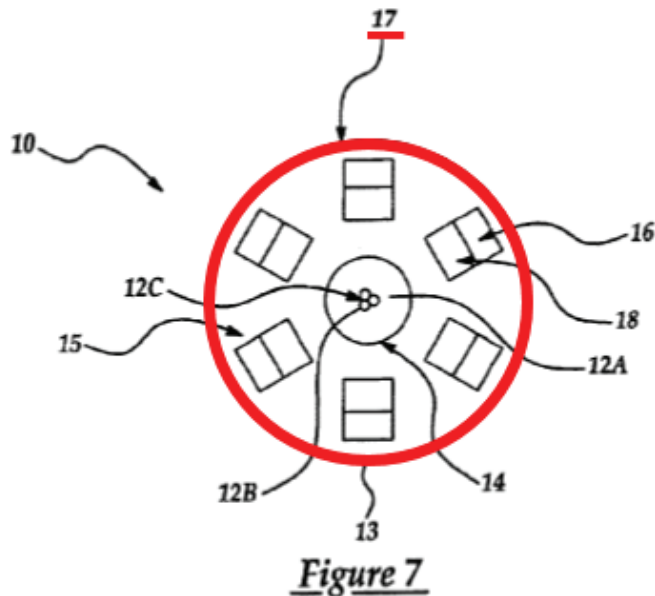
APPLE-1006, [0026], [0030]; APPLE-1014, [0025]. Additionally, a POSITA would have appreciated that the lens/protrusion in the Aizawa-Inokawa combination would have provided a similar anti-slippage advantage due to the lens's convex shape, thereby providing an additional motivation for a POSITA to make the above-noted modification of Aizawa in view of Inokawa's lens.

132. The resulting Aizawa-Inokawa-Ohsaki combination satisfies all remaining elements of claims 1-14, 16, 17, 19-23, and 26-29 in the same manner as previously described in Ground 1A, which is herein incorporated by reference.

X. GROUND 1C – Claims 23-24 Are Rendered Obvious by Aizawa in view of Inokawa and Mendelson-2006

A. Claim 23

[23] The noninvasive optical physiological measurement device of claim 1, wherein the noninvasive optical physiological measurement device is comprised as part of a mobile monitoring device.



APPLE-1025, FIG. 7, 9:34-36

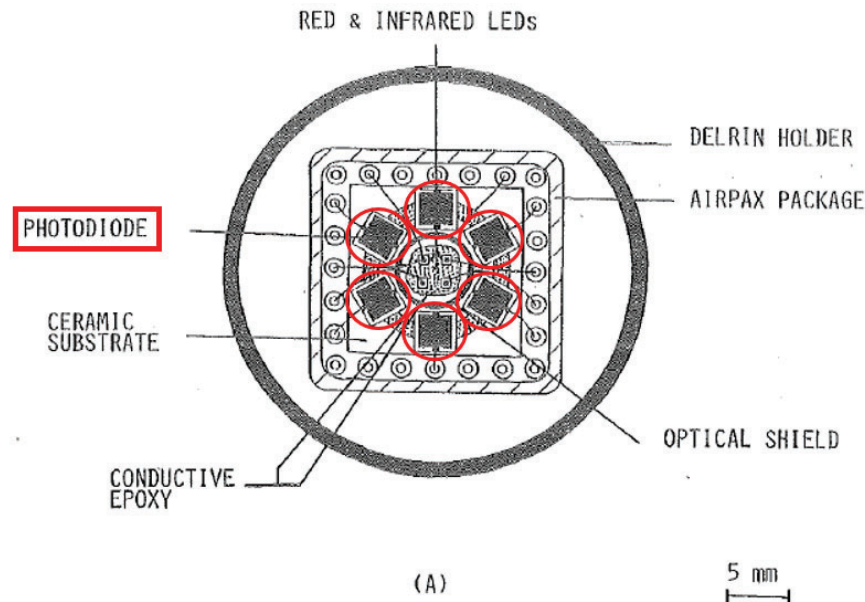
162. A POSITA would have found it obvious and actually quite routine to use a differently shaped housing, namely a circular one. *Id.* Indeed, using a circular housing having a circular raised edge, as evidenced by Mendelson-'799, was common practice well before the Critical Date, and there was nothing new or inventive about changing one housing shape for another.

[1c] at least four detectors arranged on the surface and spaced apart from each other, the at least four detectors configured to output one or more signals responsive to light from the one or more light emitters attenuated by body tissue, the one or more signals indicative of a physiological parameter of the wearer; and

163. Mendelson-1988 teaches “six silicon photodiodes ... arranged symmetrically in a hexagonal configuration,” as shown below, thus providing at least four detectors as claimed. APPLE-1015, 168. Output from the detectors are “current

pulses ... which correspond to the red and infrared light intensities reflected from the skin” and are processed to respective photoplethysmographic waveforms.

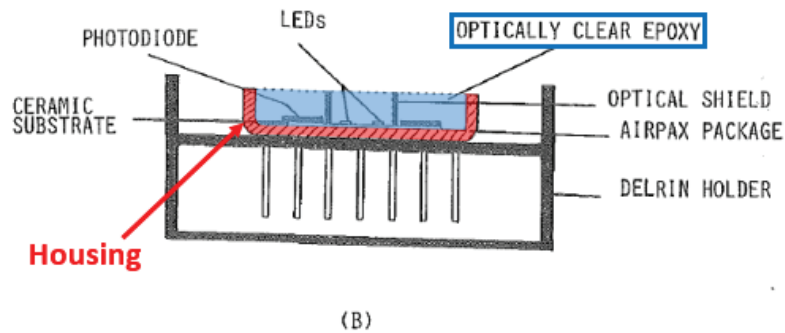
APPLE-1015, 169. Moreover, the detectors are arranged on the surface provided by the ceramic substrate. APPLE-1015, 168; FIG. 2(B).



APPLE-1015, FIG. 2(A)

[1d] a light permeable cover arranged above at least a portion of the housing, the light permeable cover comprising a protrusion arranged to cover the at least four detectors.

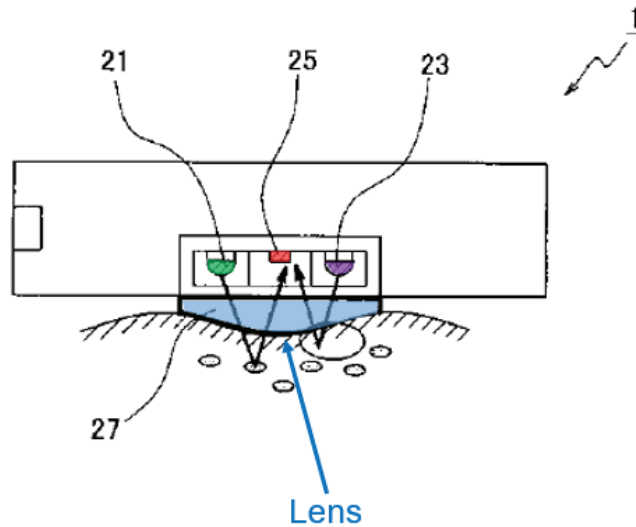
164. As shown below, Mendelson-1988 teaches encapsulating its emitters and detectors, which are within the housing (red), with an optically clear epoxy layer (blue). APPLE-1015, 168. This epoxy layer, therefore, corresponds to a light permeable cover that is arranged above the housing and covers the detectors. *Id.*



APPLE-1015, FIG. 2(b)

165. However, beyond Mendelson-1988's disclosure that this cover is made from "optically clear epoxy," Mendelson-1988 does not provide further details. Among other things, the precise shape of this layer, for instance whether it's completely flat or slightly curved, is not mentioned. It's also not mentioned whether this epoxy layer protrudes slightly above the rest of the housing to, for instance, protect the user's skin from coming in direct contact with any sharp edges of the housing. Yet a POSITA would have recognized that the shape of the epoxy layer may be formed as needed to help further Mendelson's 1988's goal of improving detection efficiency. APPLE-1015, 168, 173.

166. Indeed, as I described above, Inokawa teaches a similarly configured pulse sensor as in Mendelson-1988 but one in which a lens is positioned over the detectors to "increase the light-gathering ability of the LED as well as to protect the LED or [detector]." APPLE-1008, [0015], [0058].

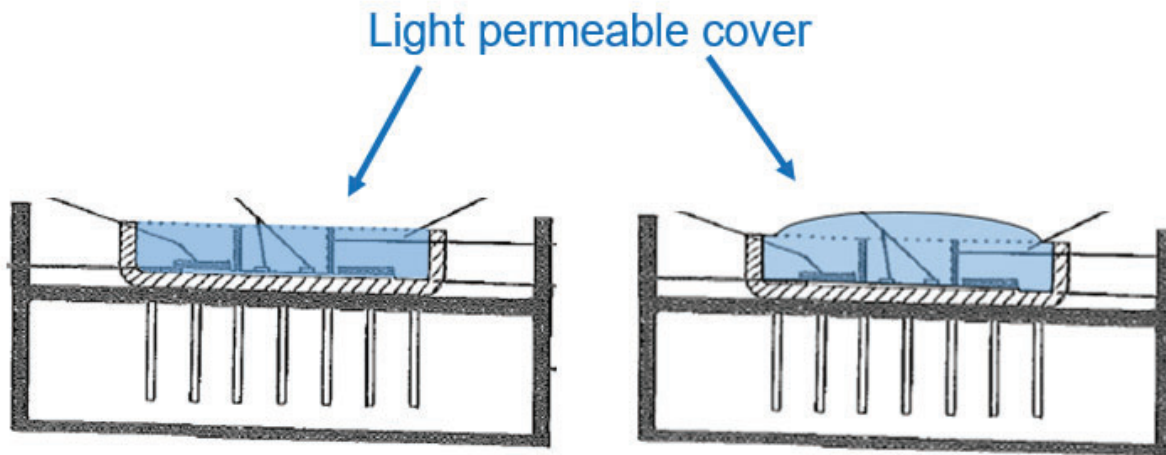


APPLE-1008, FIG. 2

167. Accordingly, a POSITA would have been motivated to incorporate the lens of Inokawa into to cover of Mendelson-1988 in order to increase the light collection efficiency. A POSITA would have been particularly interested in making such a modification because Mendelson-1988 shares a similar goal of maximizing “reflectance photoplethysmographic signals.” APPLE-1015, 173. The lens of Inokawa provides precisely this benefit to Mendelson’1988’s device by providing a protective cover that further refracts and concentrates the incoming light beams to thereby enhance the light collection efficiency. APPLE-1008, [0015], [0058].

168. Indeed, as illustrated below, the device resulting from this combination of Mendelson-1988 and Inokawa would have modified the flat epoxy cover (left) with a curved one as per Inokawa (right) to thereby “increase the light-gathering

ability.” APPLE-1008, [0015]. Here, a POSITA would have found it obvious to make the protrusion portion of the LPC—namely the lens-shaped light-gathering portion—to ensure that the light-concentration effect achieved by the lens impacts all of the detectors.



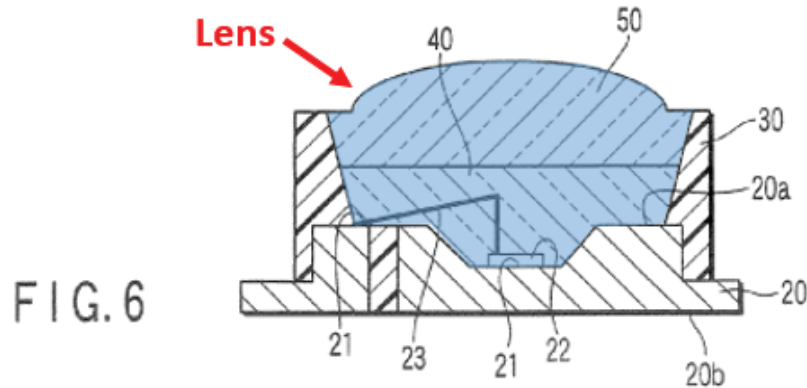
APPLE-1015, FIG. 2(B)

169. A POSITA would have understood how to implement Inokawa’s lens-shaped cover in Mendelson-1988 with a reasonable expectation of success based, among other things, on the significant overlap between these two references.

Indeed, the above-described modification would require only routine knowledge of sensor design and assembly, which were well within the skill of a POSITA prior to the Critical Date.

170. Moreover, a POSITA would have easily understood how to modify the epoxy layer of Mendelson-1988 to achieve the desired shape. Indeed, Nishikawa,

shown below, teaches that a clear epoxy layer as in Mendelson-1988 can be molded into a lens shape. APPLE-1023, [0022], [0032], [0035].

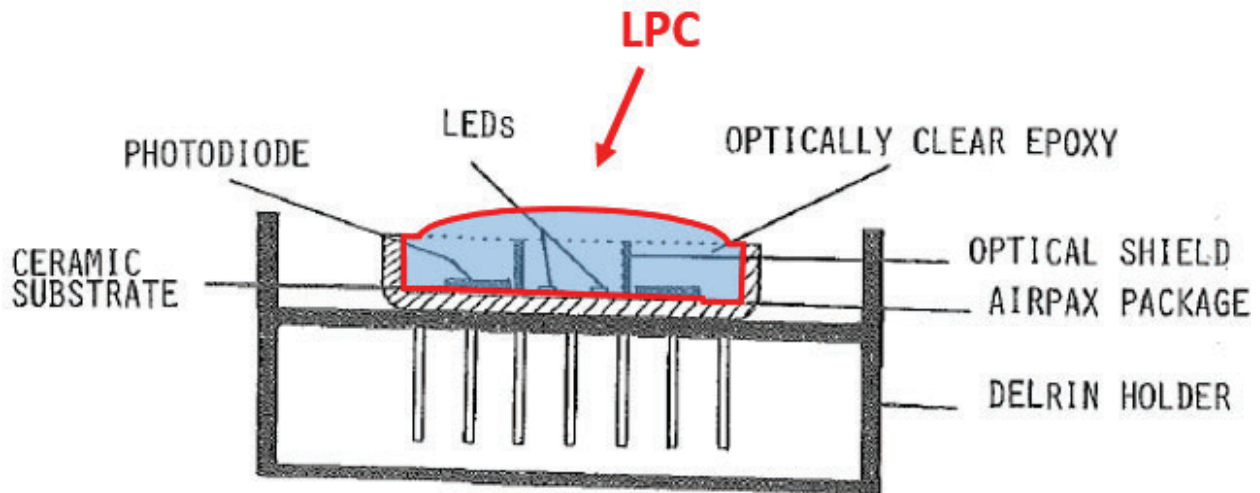


APPLE-1023, FIG. 6

171. Notably, both the optical encapsulation layer of Mendelson-1988 and the lens layer of Nishikawa are made from the same material, optically clear epoxy, and thus the interface between the encapsulation portion and the lens portion will not adversely affect the optical performance of the modified system. APPLE-1023, [0037]. Thus, to help achieve Mendelson-1988's and Inokawa's shared goal of improving light collection efficiency, a POSITA would have been motivated and able to modify Mendelson-1988's light permeable cover to have a lens shape as per Inokawa with a reasonable expectation of success.

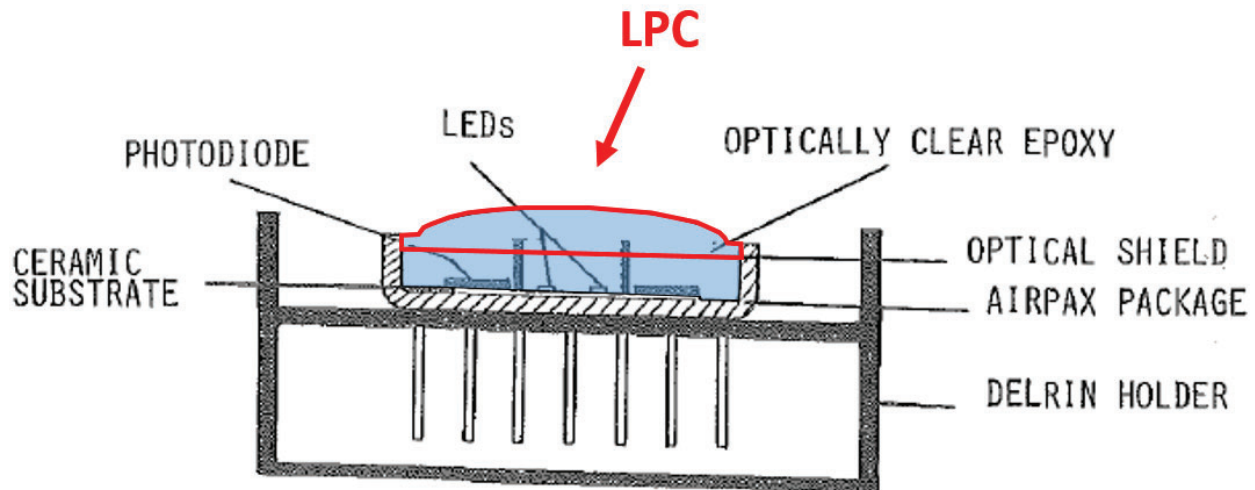
172. Here, I note that the claimed light permeable cover ("LPC") may be mapped in two different ways to the Mendelson-1988's epoxy layer as modified by Inokawa. First, the entire combined epoxy structure—*i.e.*, the sealing portion and the lens portion—may be viewed to be the LPC, as shown below. The LPC as

described in the '190 patent, for example with regard to FIG. 14D, appears to envision a similar two-part structure comprising a flat cover portion and a protruded lens portion. APPLE-1001, FIG. 14D.



APPLE-1015, FIG. 2(B)

173. Second, only the top lens portion, which lies above the underlying sealing portion, may be viewed to be the LPC having a protrusion. In forming this two-part structure, a POSITA would have been able to use the top portion of the housing (indicated below in purple), as in Nishikawa, to help form the LPC portion on top of the sealing portion. APPLE-1023, [0034]-[0038], FIGS. 5-6.

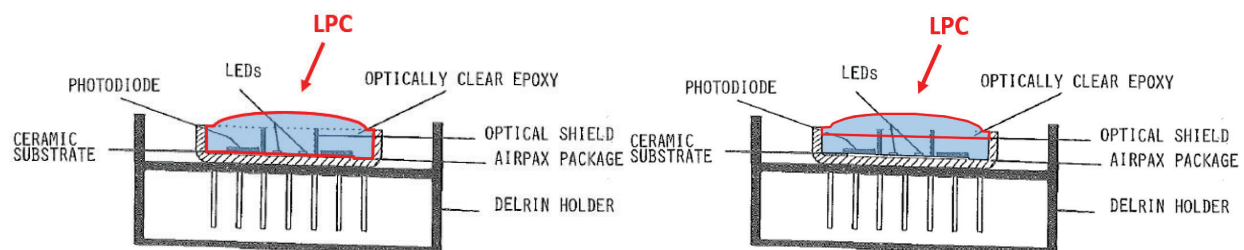


APPLE-1015, FIG. 2(B)

B. Claim 2

[2] The noninvasive optical physiological measurement device of claim 1, wherein the light permeable cover is attached to the housing and forms an airtight or substantially airtight seal enclosing the at least four detectors.

174. As explained above with respect to element [1d] and shown below, the modified LPC in the Mendelson-1988-Inokoawa combination, under either mapping, completely encapsulates and seals the detectors.



APPLE-1015, FIG. 2(B)

175. A POSITA would have recognized or found it obvious that such an encapsulating layer would provide a substantially airtight seal. APPLE-1023, Abstract. Moreover, a POSITA would have recognized that a body-worn device as

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Poeze et al.
U.S. Patent No.: 10,376,190 Attorney Docket No.: 50095-0010IP1
Issue Date: August 13, 2019
Appl. Serial No.: 16/409,304
Filing Date: May 10, 2019
Title: MULTI-STREAM DATA COLLECTION SYSTEM
FOR NONINVASIVE MEASUREMENT OF
BLOOD CONSTITUENTS

SECOND DECLARATION OF DR. THOMAS W. KENNY

I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of the Title 18 of the United States Code.

Dated: November 27, 2021

By: _____

Thomas W. Kenny, Ph.D.

4. I have no financial interest in the party or in the outcome of this proceeding. I am being compensated for my work as an expert on an hourly basis. My compensation is not dependent on the outcome of these proceedings or the content of my opinions.

5. In writing this declaration, I have considered the following: my own knowledge and experience, including my work experience in the fields of mechanical engineering, computer science, biomedical engineering, and electrical engineer; my experience in teaching those subjects; and my experience in working with others involved in those fields. In addition, I have analyzed various publications and materials, in addition to other materials I cite in my declaration.

6. My opinions, as explained below, are based on my education, experience, and expertise in the fields relating to the '190 Patent. Unless otherwise stated, my testimony below refers to the knowledge of one of ordinary skill in the fields as of the Critical Date, or before.

II. Ground 1 Establishes Obviousness

A. Inokawa's lens enhances the light-gathering ability of Aizawa

7. As I previously explained in the Original Declaration, Inokawa *very generally* describes a “lens [that] makes it possible to increase the light-gathering ability” of a reflectance type pulse sensor, APPLE-1008, [0015], [0058], FIG. 2, and, based on this disclosure, a POSITA would have been motivated to incorporate “an Inokawa-like lens into the cover of Aizawa to increase the light collection efficiency....” APPLE-1003, ¶¶80-87. In a significant extrapolation from the very simple and

purely illustrative description in Inokawa, Patent Owner provides two incorrect arguments. First, Patent Owner claims that Inokawa's disclosure is narrowly-limited to a particular lens that somehow is only capable of operation with peripheral emitters and a central detector. Second, the Patent Owner claims that the lens of Inokawa directs all incoming light rays "to the center of the sensor" and would "direct light *away* from the *periphery*-located detectors as in Aizawa," regardless of the direction of light propagation of each ray, which is a violation of elementary laws of light propagation that would be familiar to a POSITA. POR, 16, 20; *see also* APPLE-1034, 40:4-11 ("...as I describe in my Declaration...if you have a convex surface...*all light reflected* or otherwise would be condensed or directed towards the center."). Based on these two incorrect claims, the Patent Owner insists that there would be no motivation to combine.

8. Patent Owner's misinformed understanding of Inokawa's lens as well as lenses in general is demonstrated by their description of Inokawa's lens 27 as "focus[ing] light from LEDs (21, 23)...*to a single detector (25) in the center*" and "direct[ing] incoming light *to the centrally located detector*." POR, 14; *see also* APPLE-1034, 40:4-11 ("...as I describe in my Declaration...if you have a convex surface...*all light reflected* or otherwise would be condensed or directed towards the center.").

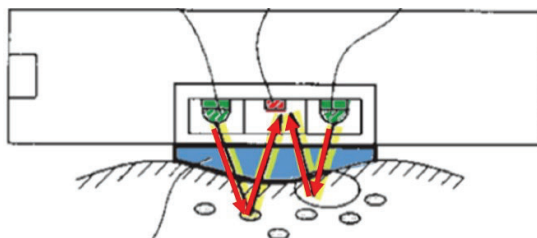
9. A correct understanding of Inokawa's lens as well as of reflectance type pulse sensors in general (like those disclosed by each of Aizawa, Inokawa, and Mendelson-1988) readily exposes Patent Owner's flawed rationale. Indeed, as I noted during

deposition, a POSITA would understand that Inokawa's lens generally improves "light concentration at pretty much all of the locations under the curvature of the lens," as opposed to only at a single point at the center as asserted by Patent Owner. Ex. 2006, 164:8-16. Indeed, as further explained below, a POSITA would have understood the following to be true—that a cover featuring a convex protrusion would improve Aizawa's signal-to-noise ratio by causing more light backscattered from tissue to strike Aizawa's photodetectors than would have with a flat cover. APPLE-1051, 52, 86, 90; APPLE-1052, 84, 87-92, 135-141; APPLE-1046, 803-805; APPLE-1006, FIGS. 1(a)-1(b). The convex cover enhances the light-gathering ability of Aizawa's sensor.

i. Masimo ignores the well-known principle of reversibility

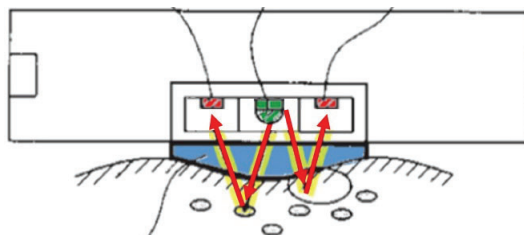
10. The well-known optical *principle of reversibility* readily dispels Masimo's claim that "a convex cover condenses light towards the center of the sensor and away from the periphery," when applied to Aizawa. POR, 16; APPLE-1052, 87-92; APPLE-1049, 106-111. Specifically, according to the principle of reversibility, "a ray going from P to S will trace the same route as one from S to P." APPLE-1052, 92, 84; APPLE-1049, 101, 110; APPLE-1036, 80:20-82:20. Importantly, the principle dictates that rays that are not completely absorbed by user tissue will propagate in a reversible manner. In other words, every ray that completes a path through tissue from an LED to a detector would trace an identical path through that tissue in reverse, if the positions of the LED emitting the ray and the receiving detector were swapped.

APPLE-1052, 92. To help explain, I have annotated Inokawa's FIG. 2 (presented below) to illustrate the principle of reversibility applied in the context of a reflective optical physiological monitor. As shown, Inokawa's FIG. 2, illustrates two example ray paths from surrounding LEDs (green) to a central detector (red):



APPLE-1008, FIG. 2 (annotated)

11. As a consequence of the principle of reversibility, a POSITA would have understood that if the LED/detector configuration were swapped, as in Aizawa, the two example rays would travel identical paths in reverse, from a central LED (red) to surrounding detectors (green). A POSITA would have understood that, for these rays, any condensing/directing/focusing benefit achieved by Inokawa's cover (blue) under the original configuration would be identically achieved under the reversed configuration:



APPLE-1008, FIG. 2 (annotated)

12. When factoring in additional scattering that may occur when light is reflected within human tissue, reversibility holds for each of the rays that are not completely absorbed; consequently, "if we're concerned with the impact of the lens on the system,

it's absolutely reversible." EX. 2006, 209:19-21, 207:9-209:21 ("one could look at any particular randomly scattered path...and the reversibility principle applies to all of the pieces [of that path] and, therefore, applies to the aggregate").

13. An example of reversibility in a situation with diffuse light, such as is present when LEDs illuminate tissue, is shown below from Hecht's Figure 4.12.

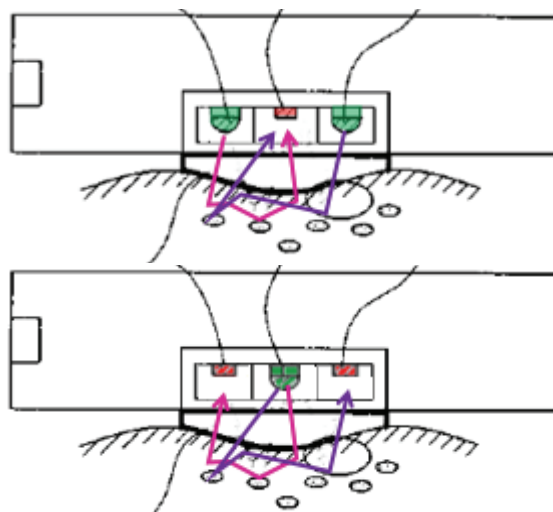


Figure 4.12 (a) Specular reflection. (b) Diffuse reflection. (Photos courtesy Donald Dunitz.)

14. In this figure 4.12a, collimated light is incident on a smooth surface, and exhibits specular reflection, in which parallel light rays encounter and are reflected from the surface and remain parallel. A POSITA would certainly understand specular reflection. In the case of the reflection as shown in Figure 4.12b, the random roughness of the surface scatters the incoming rays into many directions, and the resulting light would appear to be diffuse. However, even in this circumstance, the principle of reversibility applies—each individual ray can be reversed such that a ray travelling to the surface and scattered in a random direction can be followed backwards along exactly the same path.

15. In more detail, and as shown with respect to the example paths illustrated below (which include scattering within tissue), each of the countless photons

travelling through the system must abide by Fermat's principle. APPLE-1049, 106-111. Consequently, even when accounting for various random redirections and partial absorptions, each photon traveling between a detector and an LED would take the quickest (and identical) path along the segments between each scattering event, even if the positions of the detector and LED were swapped.



16. To better understand the effect of a convex lens on the propagation of light rays towards or away from the different LEDs or detectors, the first and last segment of the light path may be representative of the light propagation of the various light rays. In the figures above, starting at the upper left, there is a pink-colored light ray emerging from the green LED and passing through the convex lens and entering the tissue. On the lower left, there is a pink-colored light ray leaving the tissue and entering the convex lens. As drawn, these rays are the same in position and orientation, except that the direction is exactly reversed. This illustration is consistent with the Principle of Reversibility as applied to this pair of possible light rays.

According to the principle of reversibility, the upper light path from the LED to the

first interaction with a corpuscle is exactly reversed. This same behavioral pattern applies to all of the segments of the many light paths that cross the interface at the surface of the convex lens. Importantly, in this example, the convex lens does not refract the incoming ray in a different direction from the outgoing ray, e.g., in a direction towards the center different from the outgoing ray. As required by the principle of reversibility, this incoming ray follows the same path as the outgoing ray, except in the reverse direction. This statement is true for every segment of these light paths that crosses the interface between the tissue and the convex lens. Any ray of light that successfully traverses a path from the LED to the detector, that path already accounts for the random scattering as that scattering is what allowed the ray to go from the LED to a detector along the path to thereby be subsequently detected by the detector. A POSITA would have understood that the path is an aggregation of multiple segments and that the path is reversible as each of its segments would be reversible, consistent with Fermat's principle.

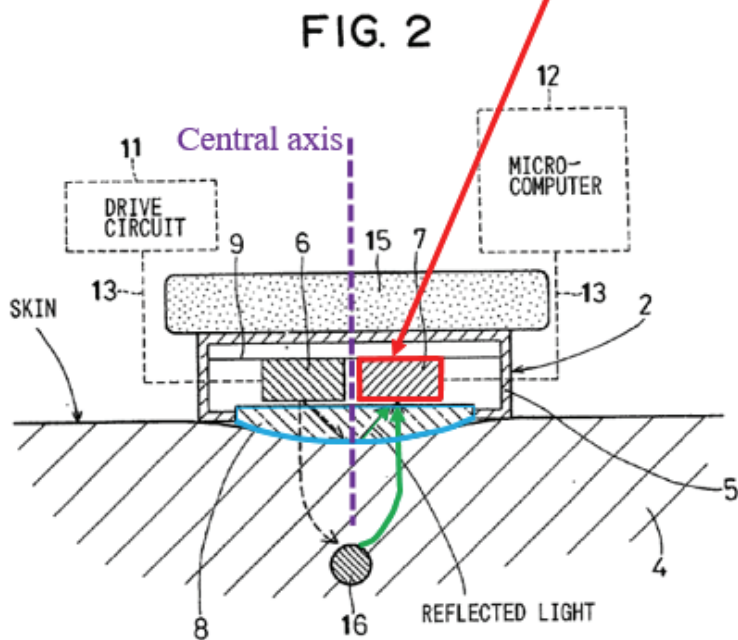
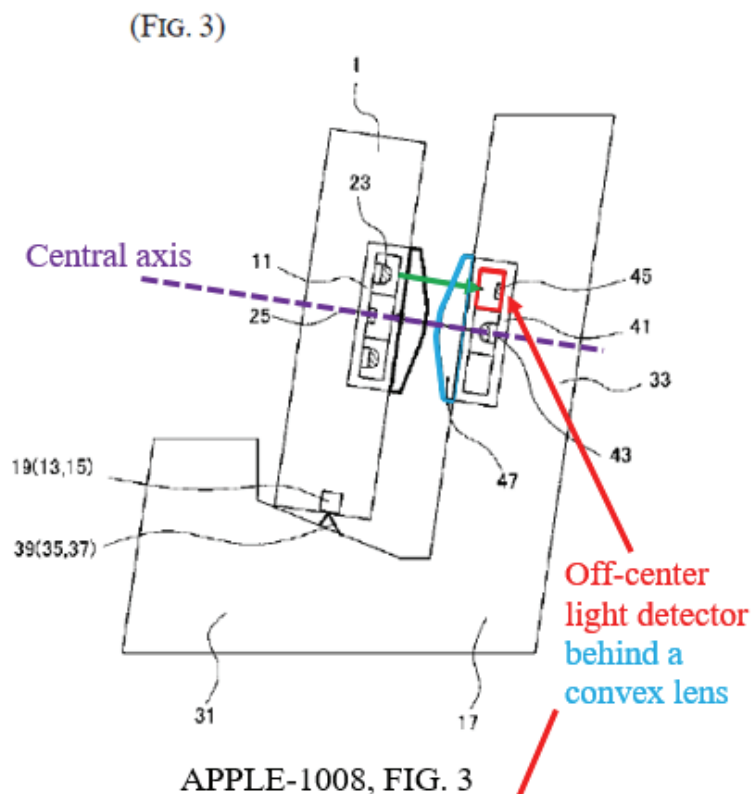
17. The statement about the reversibility of the segments of the light path which cross the interface between tissue and convex lens is consistent with the well-known and well-established Snell's law, which provides a simple algebraic relation between the angles of incidence and refraction as determined by the two indices of refraction. And Snell's law supports the basic understanding that the path of the light rays to/from a scattering event across the interface to/from the convex lens and on to/from the LED or photodetector must be reversible.

18. Based on this understanding of light rays and Snell's law, a POSITA would have understood that the positions of the emitters and detectors can be swapped in the proposed combination, and that the light paths from the initial situation would be reversed in the altered situation.

19. When confronted with this basic principle of reversibility during deposition, Dr. Madisetti refused to acknowledge it, even going so far as to express ignorance of "Fermat's principle, *whatever that is*." APPLE-1034, 89:12-19. Yet Fermat's principle, which states that a path taken by a light ray between two points is one that can be traveled in the least time, regardless of the direction of travel, is one of the most fundamental concepts in optics/physics and plainly requires the basic principle of reversibility. APPLE-1052, 87-92; APPLE-1049, 106-111. This is in no way a new theory, as this core concept dates back many years, and is offered in Aizawa itself. Indeed, *Aizawa recognizes this reversibility*, stating that while the configurations depicted include a central emitter surrounded by detectors, the "same effect can be obtained when...a plurality of light emitting diodes 21 are disposed around the photodetector 22." APPLE-1006, [0033]; EX. 2006, 209:19-21.

20. Masimo's technically and factually flawed argument is exposed by multiple prior art references, including the Ohsaki and Inokawa references which are the key elements of our combinations. As shown in the figures below, Ohsaki and Inokawa both show embodiments which use a convex lens to direct light to detectors that are not located at the center of a sensor. APPLE-1014, FIG. 2; APPLE-1008, FIG. 3.

In Inokawa's Figure 2, an off-center emitter and sensor are configured to send and receive text messages, and are capable of success, even though the detector is not positioned at the center.



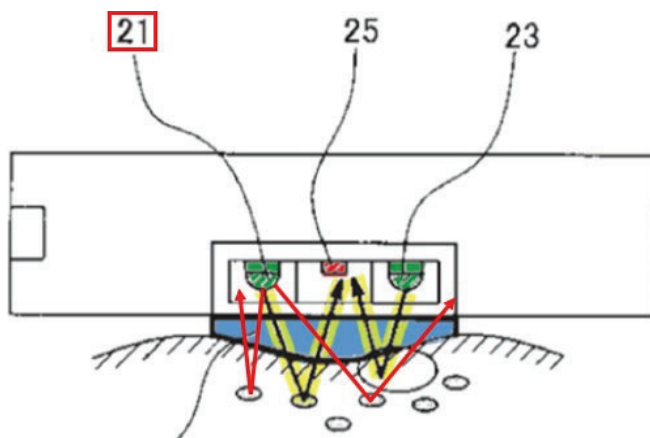
21. If, as asserted by the Patent Owner, a convex lens is required to condense, direct, or focus the light to the center, the embodiments disclosed by Ohsaki and Inokawa would all fail because there is no detector at the center to detect all of the light that would be directed towards the center by the convex board. The Ohsaki and Inokawa embodiments (reproduced above) do not show or otherwise teach that its convex board directs all light towards the center.

22. In short, based at least on the principle of reversibility, a POSITA would have understood that both configurations of LEDs and detectors—*i.e.*, with the LED at the center as in Aizawa or with the detector at the center as in Inokawa—would identically benefit from the enhanced light-gathering ability of a convex lens/protrusion.

ii. Masimo ignores the behavior of scattered light in a reflectance-type pulse sensor

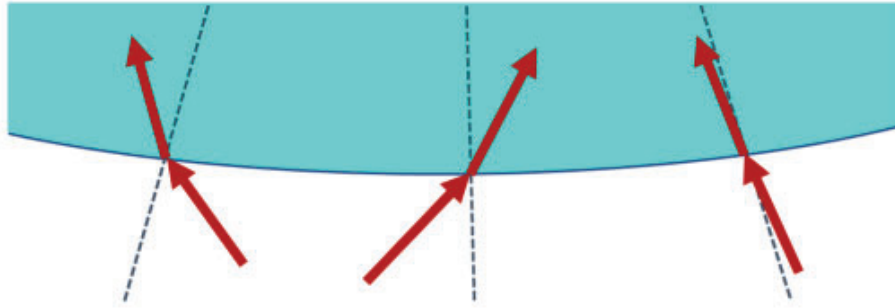
23. Because Aizawa is a reflectance-type pulse sensor that receives diffuse, backscattered light from the measurement site, its cover/lens cannot focus all incoming light toward the sensor's center. Ex. 2006, 163:12-164:2 (“A lens in general...doesn't produce a single focal point”). Indeed, reflectance-type sensors work by detecting light that has been “partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector.” APPLE-1051, 86. A POSITA would have understood that light which backscatters from the measurement site after diffusing through tissue reaches the active detection area from various random directions and angles. APPLE-1046, 803; APPLE-1051, 90, 52.

24. As noted above, basic law of refraction, namely Snell's law, dictates this behavior of light. APPLE-1052, 84; APPLE-1049, 101; APPLE-1036, 80:20-82:20; APPLE-1051, 52, 86, 90. For example, referring to Masimo's version of Inokawa's FIG. 2, further annotated below to show additional rays of light emitted from LED 21, it is clearly seen how some of the reflected/scattered light from the measurement site does not reach Inokawa's centrally located detector:



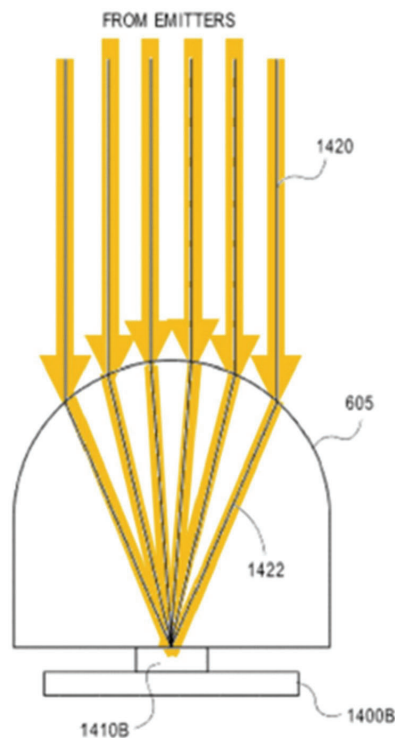
APPLE-1008, FIG. 2 (annotated); POR, 14.

25. For these and countless other rays that are not shown, there is simply no way for a cover to focus all light at the center of the sensor device. APPLE-1052, 84; APPLE-1049, 101; APPLE-1036, 80:20-82:20. The illustration I provide below shows how Snell's law determines a direction of a backscattered ray within a convex cover, thus providing a stark contrast to Masimo's assertions that all such rays must be redirected to or towards the center:



26. Indeed, far from focusing light to the center as Masimo contends, Ohsaki's convex cover provides a slight refracting effect, such that light rays that may have otherwise missed the detection area are instead directed toward that area as they pass through the interface provided by the cover. This is particularly true in configurations like Aizawa's in which light detectors are arranged symmetrically about a central light source, so as to enable backscattered light to be detected within a circular active detection area surrounding that source. APPLE-1051, 86, 90. The slight refracting effect is a consequence of the similar indices of refraction between human tissue and a typical cover material (e.g., acrylic). APPLE-1044, 1486; APPLE-1045, 1484).

27. To support the misguided notion that a convex cover focuses all incoming light at the center, Masimo relies heavily on the '190 Patent's FIG. 14B (reproduced below):



APPLE-1001, FIG. 14B (as annotated at POR, 26)

28. Masimo and Dr. Madisetti treat this figure as an illustration of the behavior of all convex surfaces with respect to all types of light, and conclude that “a convex surface condenses light away from the periphery and towards the sensor’s center.” POR, 26; APPLE-1034 (“...a POSA viewing [FIG. 14B]...would understand that light, *all light*, light from the measurement site is being focused towards the center”).
29. But the incoming collimated light shown in FIG. 14B is not an accurate representation of light that has been reflected from a tissue measurement site. The light rays (1420) shown in FIG. 14B are collimated (i.e., travelling paths parallel to one another), and each light ray’s path is perpendicular to the detecting surface.
30. While each of Inokawa, Aizawa, and Mendelson-1988 are directed to a reflectance-type pulse sensor that detects light that has been backscattered from the

measurement site, the scenario depicted in FIG. 14B shows a transmittance-type configuration where collimated or nearly-collimated light is “attenuated by body tissue,” not backscattered by it. APPLE-1001, 33:65-67. Indeed, FIG. 14I of the '190 Patent puts FIG. 14B in proper context, showing how light from the emitters is transmitted through the entire finger/tissue before being received by the detectors on the other side:

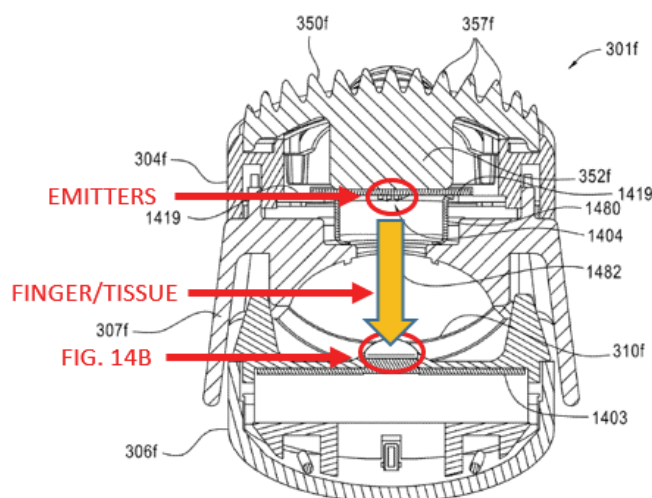
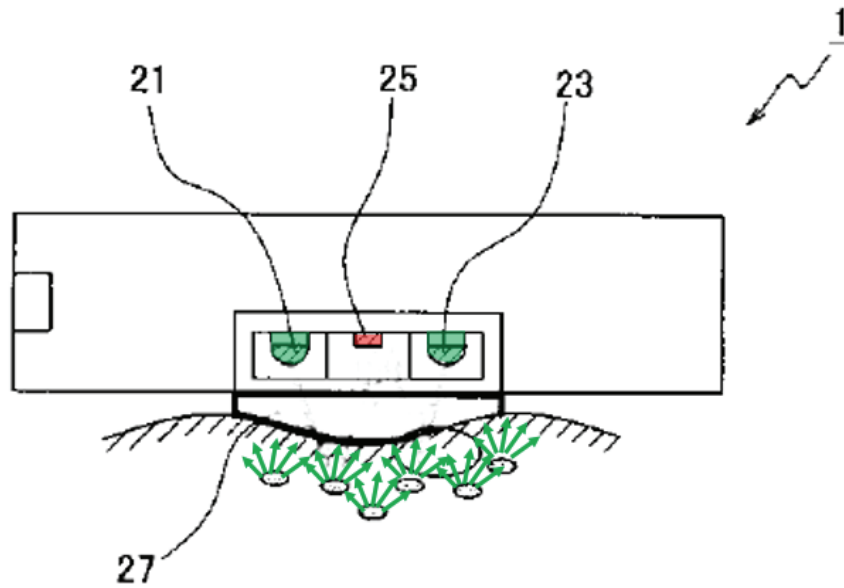


FIG. 14I

31. By contrast, the detector(s) of reflectance type pulse detectors detect light that has been “partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector.” APPLE-1051, 86. For example, a POSITA would have understood from Aizawa’s FIG. 1(a) that light that backscatters from the measurement site after diffusing through tissue reaches the circular active detection area provided by Aizawa’s detectors from various random directions and angles, as opposed to all light entering from the same direction and at

the same angle as shown above in FIG. 14B. APPLE-1051, 52, 86, 90; APPLE-1046, 803-805; *see also* APPLE-1012, FIG. 7. Even for the collimated light shown in FIG. 14B, the focusing of light at the center only occurs if the light beam also happens to be perfectly aligned with the axis of symmetry of the lens. If for example, collimated light were to enter the FIG. 14B lens at any other angle, the light would focus at a different location in the focal plane. Further, if the light were not collimated, so that rays enter the lens with a very wide range of incident angles, there would be no focus at all, and many rays will be deflected away from the center. Moreover, since “the center” takes up a very small portion of the total area under the lens, the majority of rays associated with diffuse light entering the lens would arrive at locations away from the center.

32. The light rays from a diffuse light source, such as the LED-illuminated tissue near a pulse wave sensor or a pulse oximeter, include a very wide range of angles and directions, and cannot be focused to a single point/area with optical elements such as lenses and more general convex surfaces. The example figure below illustrates light rays backscattered by tissue toward a convex lens; as consequence of this backscattering, a POSITA would have understood that the backscattered light will encounter the interface provided by the convex board/lens at all locations from a wide range of angles. This pattern of incoming light cannot be focused by a convex lens towards any single location.



APPLE-1052, 141 (annotated)

33. To the extent Masimo contends that only *some* light is directed “towards the center” and away from Aizawa’s detectors in a way that discourages combination, such arguments also fail. Indeed, far from *focusing* light to a single central point, a POSITA would have understood that Ohsaki’s cover provides a slight refracting effect, such that light rays that may have missed the active detection area are instead directed toward that area as they pass through the interface provided by the lens.

APPLE-1051, 52; APPLE-1007, [0015]; APPLE-1052, 87-92, 135-141; APPLE-1034, 60:7-61:6, 70:8-18.

34. Patent Owner and Dr. Madisetti’s reliance on drawings provided in paragraphs 119-120 of my Original Declaration filed in IPR2020-01520 for justification of their understanding of Inokawa’s lens is similarly misplaced. POR, 16-18; APPLE-1041, 41:7-22, 60:7-61:6. Far from demonstrating the false notion that a convex lens directs all light to the center, these drawings I previously provided are merely

simplified diagrams included to illustrate, as per dependent claim 12, one example scenario (based on just one ray and one corpuscle) where a light permeable cover can “reduce a mean path length of light traveling to the at least four detectors.” Ex. 2020, ¶¶119-120. As previously illustrated, there are many other rays that would intersect the interface between the tissue and the lens at different locations and with different angles of incidence, and the effect of the lens on this variety of rays is not nearly as simple as the statements provided by Dr. Madisetti. There is simply no possibility of any lens focusing all incoming rays from a diffuse light source toward a central location.

B. It would have been obvious to modify Aizawa in view of Ohsaki to include a convex protrusion

35. As explained in my Original Declaration, “Ohsaki teaches that adding a convex surface...can help prevent the device from slipping on the tissue of the wearer compared to using a flat cover without such protrusion” and that “a POSITA seeking to achieve improved adhesion between the detector and the skin, as expressly recognized in Aizawa, would have been motivated and readily able to modify Aizawa’s acrylic plate to have a convex shape as in Ohsaki.” APPLE-1003, ¶¶130-131 (citing to APPLE-1014, [0025]; APPLE-1006, [0026], [0030]).

36. Patent Owner, rather than attempting to directly rebut this rationale, focuses on arguments that are factually flawed and legally irrelevant. Specifically, Patent Owner contends that Ohsaki’s “convex surface must have *longitudinal directionality*,” and that “Ohsaki indicates that its convex surface *only prevents*

slipping on the backhand side (i.e., watch-side) of the user’s wrist.” POR, 39.

Patent Owner further asserts that the shape of Ohsaki’s board must be limited to a long, narrow rectangular shape while ignoring that the specification includes no specific limitation on the shape of the board.

37. Notably absent from the POR is how Ohsaki *actually* describes the benefits associated with its convex surface. For example, Ohsaki contrasts a “convex detecting surface” from a “flat detecting surface,” and explains that “if the translucent board 8 has a flat surface, the detected pulse wave is adversely affected by the movement of the user’s wrist,” but that if “the translucent board 8 has a convex surface...variation of the amount of the reflected light...that reaches the light receiving element 7 is suppressed.” APPLE-1014, ¶[0025]. But a POSITA would have understood from such teachings of Ohsaki that the advantages of a light permeable protruding convex cover could apply regardless of any alleged longitudinal directionality of Ohsaki’s cover and regardless of where on the body such a convex cover was placed. *See* APPLE-1014, ¶¶[0015], [0017], [0025], FIGS. 1, 2, 4A, 4B. This is because Ohsaki was relied upon not for its exact cover configuration but rather for the rather obvious concept that a convex surface protruding into a user’s skin will prevent slippage, regardless of any directionality that may or may not exist with respect to such convex surface and regardless of where on the human body it is located. *See* Ex. 2012, 91, 87; APPLE-1014, ¶¶[0015], [0017], [0025], FIGS. 1, 2, 4A, 4B. In fact, Ohsaki says nothing about the

exact dimensions or even anything specific about the required shape of the board, except that it provides a convex protrusion. A POSITA would seek to combine the board of Ohsaki with Aizawa by making reasonable modifications as needed to ensure that the board of Ohsaki was compatible with the other features present in Aizawa. A POSITA would find it obvious to consider selecting a shape for the board that is consistent with the shape of the system presented in Aizawa, and would expect that the benefits associated with the convex board of Ohsaki would be present in the combination. And adding a convex surface to Aizawa's flat plate will serve to *improve* its tendency to not slip off, not take away from it, since it is well understood that physically extending into the tissue and displacing the tissue with a protrusion provides an additional adhesive effect. Aizawa provides a plate that improves adhesion with the surface. Ohsaki further teaches that the convex protrusion provides "intimate contact" with the tissue, which helps prevent the detecting element from slipping off. These benefits are clearly related and complimentary, and a POSITA would appreciate that modifying the plate of Aizawa to include a convex protrusion as in Ohsaki would provide improved performance, and that these benefits can be obtained by making obvious modifications to the board in Ohsaki to accommodate the shape of Aizawa.

38. Indeed, Ohsaki's specification and claim language reinforce that Ohsaki's description would not have been understood as limited to one side of the wrist. For example, Ohsaki explains that "the detecting element 2...may be worn on the back

side of the user's forearm” as one form of modification. *See* APPLE-1014, [0030], [0028] (providing a section titled “[m]odifications”). The gap between the ulna and radius bones at the forearm is even greater than the gap between bones at the wrist, which is already wide enough to easily accommodate a range of sensor sizes and shapes, including circular shapes. In addition, Ohsaki’s claim 1 states that “the detecting element is constructed to be worn on a back side of a user’s wrist *or a user’s forearm.*” *See also* APPLE-1014, claims 1-2. As another example, Ohsaki’s independent claim 5 and dependent claim 6 state that “the detecting element is constructed to be worn on a user’s wrist or a user’s forearm,” *without even mentioning a backside* of the wrist or forearm. *See also* APPLE-1014, Claims 6-8. A POSITA would have understood that Ohsaki’s benefits provide improvements when the sensor is placed on either side of the user’s wrist or forearm. APPLE-1014, [0025], FIGS. 4A, 4B. And while Masimo appears to contend that Ohsaki teaches that a convex cover at the front (palm) side of the wrist somehow *increases* the tendency to slip, this is an argument that is nowhere supported by Ohsaki. For instance, paragraph 23 and FIGS. 3A-3B of Ohsaki that Masimo points to as allegedly providing support for this incorrect argument mentions nothing about the flat/convex nature of the cover and is instead merely demonstrating that pulse detection is generally less reliable when the user is in motion (and thus would benefit from changes such as adding a convex cover). APPLE-1014, [0024], FIGS. 4A, 4B

39. POR presents several arguments with respect to Ground 1 that are premised on

Ohsaki *requiring* the detecting element to be worn on a back side of a user's wrist or a user's forearm. Because Ohsaki requires no such location for the translucent board 8, these arguments fail.

III. Ground 2 Establishes Obviousness

40. As I further clarify below in response to Patent Owner's arguments, claims 1-14, 16-22, and 26-30 are rendered obvious by the combination of Mendelson-1988 and Inokawa (Ground 2A).

A. Inokawa's lens similarly enhances the light-gathering ability of Mendelson-1988

41. Similar to their rebuttal of the Aizawa-based grounds, Patent Owner contends that (1) "Inokawa's convex lens focused light on a *centrally located* detector" and (2) as a result, incorporating such a lens to Mendelson-1988 would cause the "lens to direct light *away* from the detectors" based on Mendelson-1988's use of centrally-located LEDs. POR, 42-46. For reasons discussed at length above, basic optical principles and a proper understanding of reflectance-type sensors as in Aizawa, Inokawa, and Mendelson-1988 would have led a POSITA to understand that adding an Inokawa-like lens to Mendelson-1988 would result in additional benefits such as enhanced light-gathering ability and improved signal-to-noise ratio. Again, as noted above, Patent Owner's fundamentally flawed characterization of the lens of Inokawa as "focusing [light] on a single central detector" runs contrary to basic principles of optics and how lenses work.

B. Mendelson-1988 in view of Inokawa includes the claimed cover

42. As I previously explained, the Mendelson-1988-Inokawa combination provides protruded epoxy cover that acts as a lens and also covers the detectors. APPLE-1003, ¶¶164-173. Patent Owner argues, however, that “the ’190 Patent distinguishes a resin on a surface from a cover” and, as a result, the modified Mendelson-1988 device lacks a cover. POR, 46-49. Patent Owner further argues that the convex cover in the contemplated combination is somehow not a cover because “it is part of an undifferentiated mass of material.” *Id.*

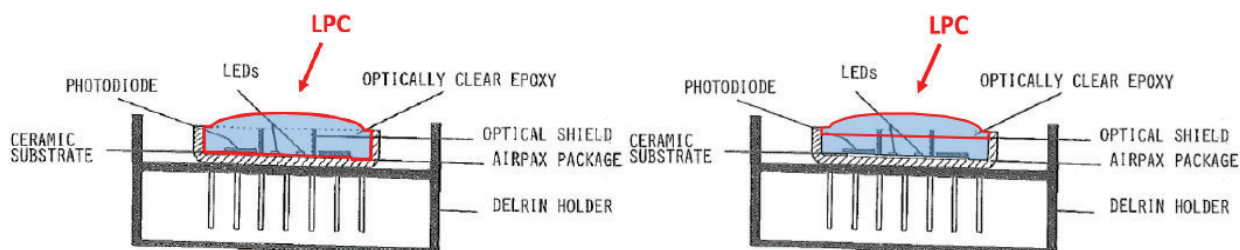
43. A POSITA would understand the plain meaning of cover to be merely “something that protects, shelters, or guards.” APPLE-1050. Both instances of the “light permeable cover” as I previously identified are clearly covers that serve to protect. There is nothing in the specification of the ’295 patent itself that suggests that some special meaning is attributed to the term “cover” as used in the patent.

44. Patent Owner mischaracterizes my deposition testimony to make it sound like I agreed that “sealing resin” is somehow different from a cover. POR, 47 (citing to Ex. 2009, 395:22-396:17). My actual testimony, if one reads it fully, clearly shows that no such statement was made. *See* Ex. 2009, 396:9-17 (“Q. So [using a sealing resin] would be one way to protect the components without using a cover, correct? A. There are many ways to protect the elements other than using a cover. The purpose of the cover in this combination is also to improve adhesion and to improve light gathering for the operation of the system.”). Rather, I was merely clarifying

that using a sealing resin is “a pretty common way to protect electronic components.” *Id.*, 395:22-396:8.

45. Moreover, while Patent Owner points to a cherry-picked passage from the '190 Patent to suggest that it distinguishes “cover” from “resin epoxies,” POR, 47 (citing APPLE-1001, 36:37-46 (“[The cover] can protect...*more effectively* than currently-available *resin epoxies*.”)), Patent Owner failed to reproduce the rest of the sentence, which reads: “...more effectively than currently-available resin epoxies, *which are sometimes applied to solder joints between conductors and detectors.*” APPLE-1001, 36:37-46. That is, the epoxy resin to which the '190 Patent compares its cover is not the epoxy cover as contemplated in the Mendelson-1988 combination but rather epoxy that is applied to solder joints.

46. As for Patent Owner’s argument that the alternative mapping of the cover shown below right is improper because the identified cover (“LPC”) is somehow “part of an *undifferentiated* mass of material,” the plain meaning of “cover” does not require that the cover be a distinct structure that is completely separated and distinct from surrounding structures. *See* APPLE-1050. Nor does Patent Owner expressly argue for such a construction of “cover.”

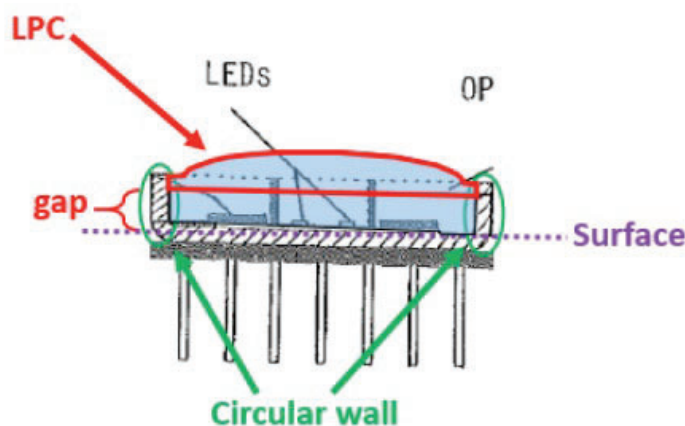


POR, 48

47. Under plain meaning, both LPCs as identified above are covers that protect the underlying components. Moreover, to the extent the claimed “cover” must be “distinct” from all other components, I previously explained how a POSITA, looking at conventional epoxy processing techniques such as those found in Nishikawa, would have added an additional epoxy lens layer separately on top of the epoxy encapsulation layer underneath, thereby providing a separate and differentiated mass of material to serve as the cover. APPLE-1003, ¶173 (citing to APPLE-1023, [0034]-[0038], FIGS. 5-6).

C. Mendelson-1988 in view of Inokawa renders obvious a “circular wall” that “creates a gap between the surface and the light permeable cover

48. For dependent claim 3, I previously explained, using annotated FIG. 2(B) of Mendelson-1988 shown below, how the claimed “gap” is created by the identified “circular wall”:



APPLE-1003, ¶¶176-179

49. Here, the height of the “circular wall” in Mendelson-1988 necessarily

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.

Petitioner,

v.

MASIMO CORPORATION,

Patent Owner.

Case IPR2021-00195
U.S. Patent 10,376,190

DECLARATION OF VIJAY K. MADISETTI, PH.D.

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| Masimo Ex. 2004 Apple v. Masimo IPR2021-00195 |
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incorporate a convex, lens-like shape as in Inokawa into Aizawa's acrylic plate to thereby increase light collection efficiency, in turn leading to more reliable pulse wave detection." Ex. 1003 ¶84. Dr. Kenny repeats that "Aizawa is modified to include a lens/protrusion (right) as per Inokawa in order to 'increase the light-gathering ability.'" Ex. 1003 ¶85 (quoting from Inokawa, Ex. 1008 ¶15).

B. Ground 1A Does Not Establish Obviousness Because A POSITA Would Not Have Been Motivated To Combine Inokawa's Convex Lens With Aizawa's Sensor

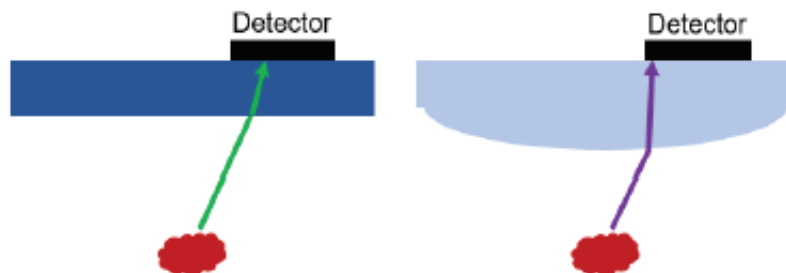
1. Dr. Kenny and Petitioner Admit That Inokawa's Convex Lens Directs Light To The Center Of The Sensor

48. Both Dr. Kenny and Petitioner agree that Inokawa's convex lens condenses light towards a centrally located detector—not periphery-located detectors like those used in Aizawa, as demonstrated by their admissions in this proceeding and their submissions in an IPR (IPR2020-01520 (Ex. 2019; Ex. 2020)) of related patent U.S. Pat. No. 10,258,265 (Ex. 2025). U.S. Pat. No. 10,258,265 and the '190 Patent share a common specification. U.S. Pat. No. 10,258,265 is at least a continuation of U.S. Patent App. No. 14/981290. The '190 Patent is at least a continuation of U.S. Patent App. No. 16/261326, which is at least a continuation of U.S. Patent App. No. 16/212537, which is at least a continuation of U.S. Patent App. No. 14/981290.

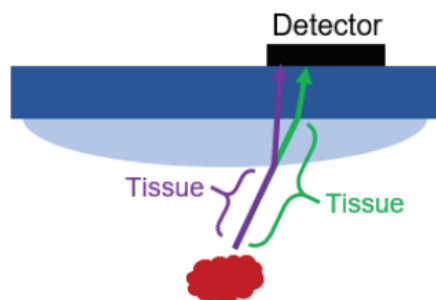
49. Petitioner included the illustrations below in its Petition in this proceeding when discussing claim 12 of the '190 Patent, as well as its Petition in

IPR2020-01520 when discussing claim 12 of U.S. Pat. No. 10,258,265. Pet. 32-33; Ex. 2019 at 45. Petitioner explained that “the lens/protrusion of Inokawa, which is used to modify Aizawa ... serves a condensing function and thus, as with any other lens, refracts light passing through it.” Pet. 32; Ex. 2019 at 44. Petitioner explained the drawing below as comparing “the length of non-refracted light (*i.e.*, without a lens, left) bouncing off an artery with that of refracted light (*i.e.*, with a lens, right).” Pet. 32-33; Ex. 2019 at 44-45. Refraction is a phenomenon related to the velocity of light in different materials because the velocity of light depends on the material through which it is traveling. Thus, the change in velocity as light moves from one material to another material may cause the light to deviate from its original direction, which is called “refraction.” I note that the illustration below shows refraction for both the flat and convex surfaces because in both instances the illustrated light ray changes direction. Moreover, I note that, as illustrated by Petitioner, the change of direction for the light ray hitting the convex surface is relatively more towards the center of the cover than for the flat cover. Petitioner states that the result of the greater refraction of light with the convex cover with a protruding surface is that “the mean path length of light traveling to the at least four detectors is reduced—that is, the purple line is shorter than the green line.” Pet. 32-33; *see also* Ex. 2019 at 45. Petitioner also includes a drawing superimposing the two drawings below to “clearly show[] the

shortened path traveled by refracted light in the presence of a protrusion/lens, both within the tissue as well as for total path length.” Pet. 33; Ex. 2019 at 45.



Petitioner’s illustration of redirection of the mean path length of light traveling to the detectors when passing through a flat (left) and convex (right) cover (Pet. 33; *see also* Ex. 2019 at 45)



Petitioner’s illustration superimposing the above refractions when illustrating how a convex surface a protruding surface changes the mean path length of incoming light (Pet. 33; *see also* Ex. 2019 at 45, 91)

50. Dr. Kenny also included and explained the two figures above in his declarations in this proceeding and IPR2020-01520 (Ex. 2020) as a way to illustrate the mean path length of light. Ex. 1003 ¶¶107-108; Ex. 2020 at 69-70. Dr. Kenny explained that, when using a protruding surface such as Inokawa’s convex lens, “the incoming light is ‘condensed’ toward the center.” Ex. 1003 ¶107; Ex. 2020 at 69-70. Dr. Kenny goes on to explain: “Laying these two

drawings on top of each other...the shortened path length within the tissue for the purple (refracted) line can be clearly seen compared to the path length within the tissue of the green (non-refracted) line.” Ex. 1003 ¶108; Ex. 2020 at 70-71.

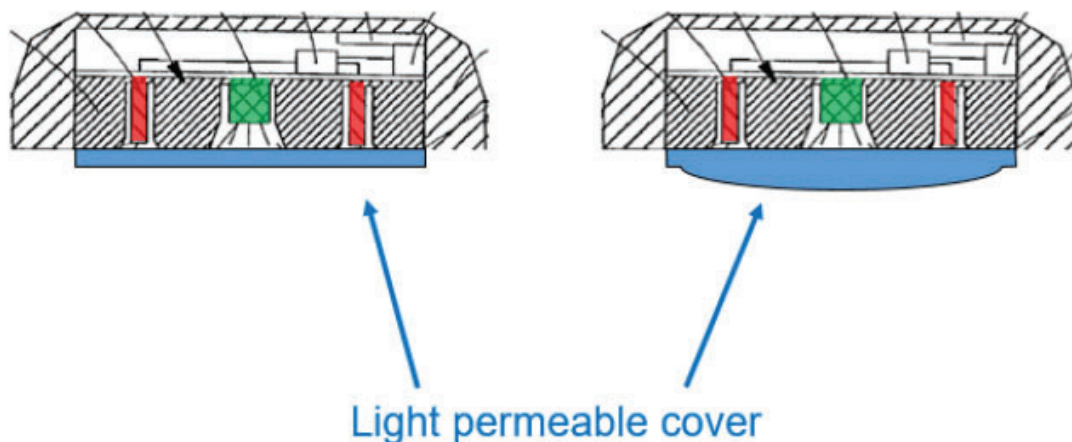
51. The understanding expressed by Petitioner and Dr. Kenny about condensing light is consistent with Inokawa’s disclosure, which uses a convex surface as a way to increase the light gathering capability for a centrally located detector. Ex. 1008 ¶[0058], Fig. 2. As shown in Figure 2 (below), Inokawa illustrates how a protruding surface placed between the sensor and the skin condenses incoming light towards the central detector 25. Ex. 1008 ¶[0058], Fig. 2. This is helpful for Inokawa’s particular sensor configuration because the emitters are located on the edges of the sensor while the detector is located in the center of the sensor. Thus, for Inokawa’s particular linear arrangement of emitter-sensor-emitter, the protruding shape is reported to increase the light gathering capabilities of the centrally located detector when collecting the light emitted by the periphery-located LEDs and reflected by the measurement site. Ex. 1008 ¶[0058], Fig. 2. Inokawa illustrates this by using arrows that illustrate the general path of light from emitters, to the measurement site, and then back towards the central detector.

central location as a result of passing through the protruding surface. Ex. 1001 Fig. 14B.

55. Thus, as discussed, Petitioner, Dr. Kenny, and the '190 Patent all support that a POSITA would have understood that the protruding surface illustrated by Inokawa would direct incoming light towards the center of the sensor. I also agree that a POSITA reading Inokawa would have understood that the protruding surface illustrated by Inokawa would direct incoming light towards the center of the sensor.

2. A POSITA Would Not Have Been Motivated To Direct Light Away From Aizawa's Detectors And Would Have No Reasonable Expectation Of Success When Doing So

56. Although Petitioner and Dr. Kenny both agree that a POSITA would have understood that a protruding surface would converge incoming light toward the center, I understand that Petitioner asserts that a POSITA would place Inokawa's convex lens on the sensor of Aizawa, which has the opposite configuration of components as compared to Inokawa, with peripheral detectors and a central emitter. Petitioner illustrates the result of this change in Aizawa as a device with the emitter (green) in the center and the detectors (red) on the periphery.



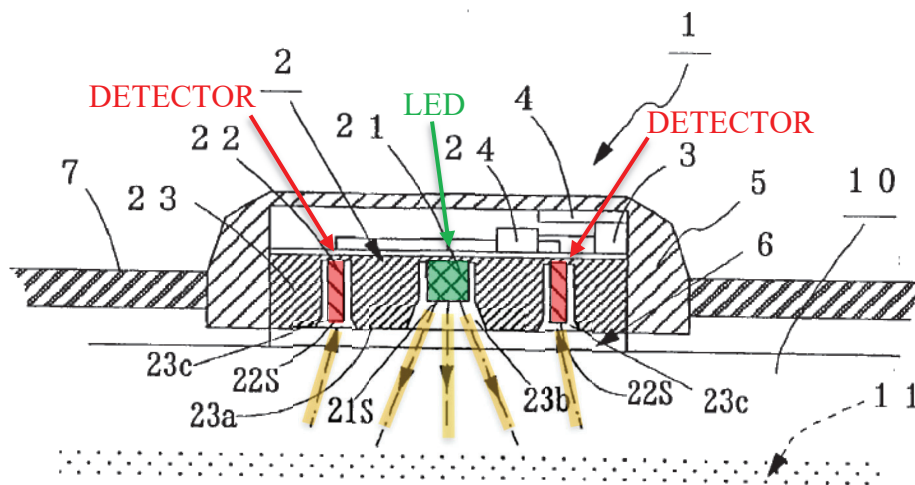
Petitioner's and Dr. Kenny's illustrations (Pet. 23; Ex. 1003 ¶85)
 Aizawa's flat surface (left) versus Ground 1A's Proposed Combination (right)
 The detectors are red and the emitter is green.

57. Dr. Kenny illustrates this same combination in his declaration. Ex. 1003 ¶85. Dr. Kenny states that “by positioning a lens above the optical components of Aizawa, as shown below, the modified cover will allow more light to be gathered and refracted toward the light receiving cavities of Aizawa, thereby further increasing the light-gathering ability of Aizawa beyond what is achieved through the tapered cavities.” Ex. 1003 ¶85. As shown in Inokawa, as well as Dr. Kenny's other figures in his declaration and the '190 Patent, however, a POSITA would not have believed that the illustrated protruding surface would have allowed “more light to be gathered and refracted toward” Aizawa's peripheral detectors. Instead, as discussed above, a POSITA reading Inokawa would have expected more light would be gathered and refracted towards the center of the sensor, which is where Aizawa positions its single emitter.

58. Like Dr. Kenny, Petitioner asserts that a POSITA would have been motivated to “further Aizawa’s objective of enhancing its light-collection efficiency.” Pet. 23. But, again, a POSITA would not have expected Inokawa’s protruding surface to accomplish this goal because, as discussed, a POSITA would have understood that a protruding surface directs light away from the periphery-located detectors. Ex. 1008 ¶[0058], Fig. 2. Thus, in view of Inokawa’s teachings of increased light gathering to its central detector, a POSITA would have believed that a protruding surface would have undesirably decreased light-collection efficiency at Aizawa’s peripheral detectors and reduced the measured optical signal. Ex. 1008 ¶[0058], Fig. 2.

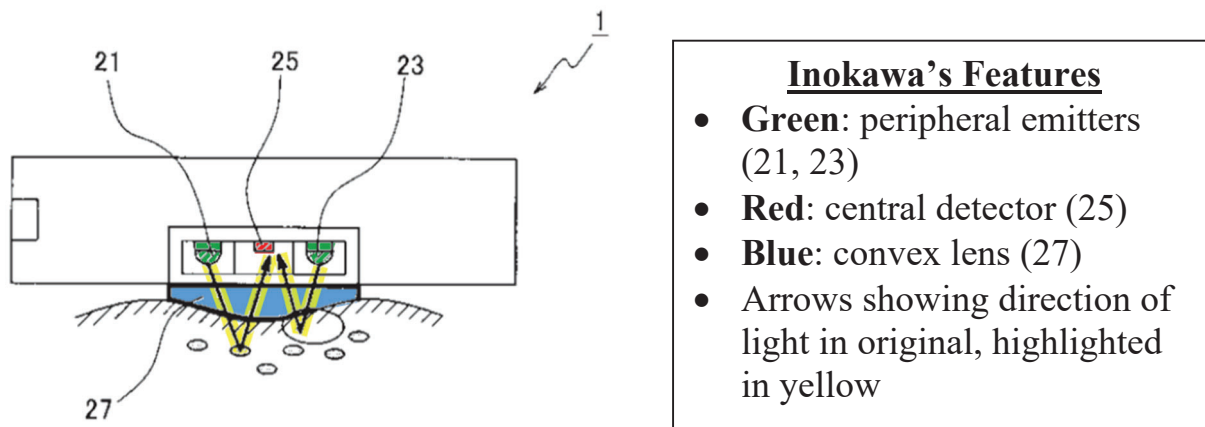
59. As illustrated in Aizawa, light is emitted from a central emitter (e.g., a light emitting diode or “LED”) and reaches detectors (e.g., photodetectors) that are disposed around the emitter. Ex. 1006 ¶[0009]. The light emitted from the center-located emitter reflects from the artery of the wrist of the user and travels to the periphery located detectors. Ex. 1006 ¶¶[0009], [0027], [0036]. Thus, as illustrated in Aizawa Figure 1B, the light reaching Aizawa’s detectors must travel in the opposite direction compared to the light in Inokawa. Ex. 1006 Fig. 1B. Aizawa states that its detectors “are disposed around the light emitting diode 21 on a circle concentric to the light emitting diode 21 in this embodiment.” Ex. 1006 ¶[0027]. Aizawa contrasts its circular arrangement of detectors around an emitter

with the type of linear arrangement illustrated in Inokawa, explaining the photodetectors “should not be disposed linearly.” Ex. 1006 ¶[0027]; *see also* ¶¶[0009], [0036]. Aizawa illustrates the light path as leaving a single centrally located emitter, passing through the body, and reflecting back to periphery-located detectors:



Aizawa Fig. 1B (cross-sectional view, color added)

60. As shown below, Inokawa illustrates the opposite emitter/detector arrangement and the opposite required light path for detection: light leaves periphery-located emitters, passes through the body, reflects back, and is focused on a single centrally located detector. Ex. 1008 ¶[0058], Fig. 2.

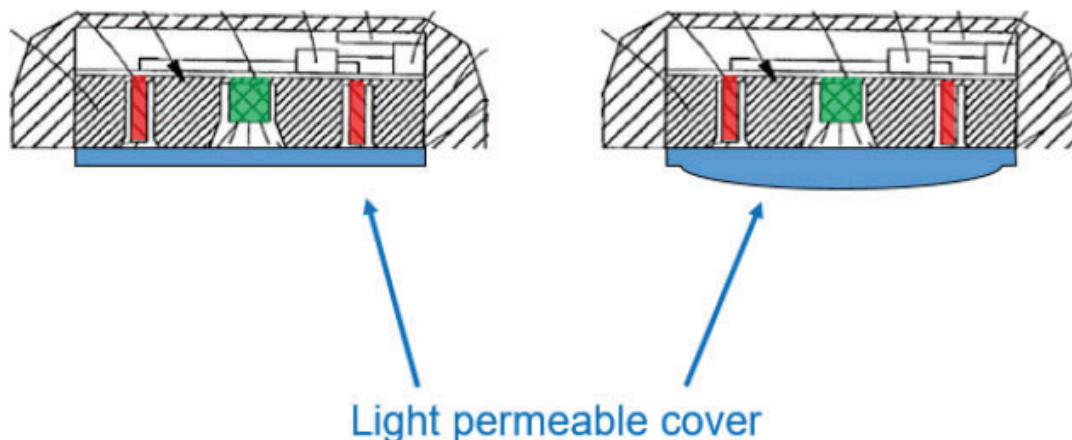


Inokawa Fig. 2 (color added)

61. In my opinion, a POSITA would have linked the benefit of increased light gathering described in Inokawa to the arrangement of peripheral emitters and center-located detector, and thus would have believed that the benefit of increased light gathering resulting from Inokawa's protruding surface made sense in view of Inokawa's configuration using a centrally located detector. Ex. 1008 ¶[0058], Fig. 2. In contrast, a POSITA would have understood that Inokawa's protruding surface would not be suitable for achieving a goal of improved light gathering in Aizawa's sensor, because Aizawa uses a circular arrangement of peripheral detectors arranged around a central emitter and contrasts its approach to a linear detector/emitter arrangement. Ex. 1006 ¶¶[0009], [0027], [0036], Fig. 1B; *see also* Figs. 1A, 2, 4, 5.

62. As shown in the structure that Dr. Kenny and Petitioner assert would have resulted from the proposed combination of Inokawa and Aizawa (reproduced below), the result of the proposed combination places the emitter at the very center

of the protruding surface, which is the position at which the returning light would be concentrated.

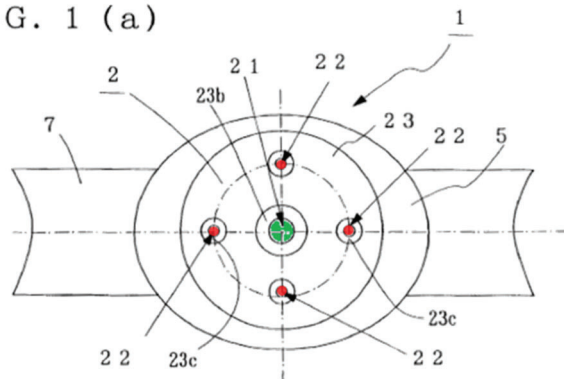


Petitioner's and Dr. Kenny's illustrations (Pet. 23; Ex. 1003 ¶85)
Aizawa's flat surface (left) versus Ground 1A's Proposed Combination (right)

63. In my opinion, a POSITA would have found this combination of a protruding surface with Aizawa's sensor particularly problematic because—consistent with Aizawa—the combination includes small detectors with small openings surrounded by a large amount of opaque material. Pet. 23; Ex. 1003 ¶85; Ex. 1006 Fig. 1B; *see also* Figs. 1A, 2, 4, 5. Aizawa's top-down view shown in Figure 1A confirms the detectors' small size. Ex. 1006 Fig. 1A; *see also* Figs. 2, 4. Aizawa Figure 1A is reproduced below with the detectors highlighted in red and the emitters highlighted in green. Aizawa explains that the openings of the detector cavities (23c in the figure below) are larger than the size of the photodetector itself, and intended to “expand...the light receiving areas of the

photodetectors... [and] are tapered such that their widths increase toward the contact face.” Ex. 1006 ¶[0024].

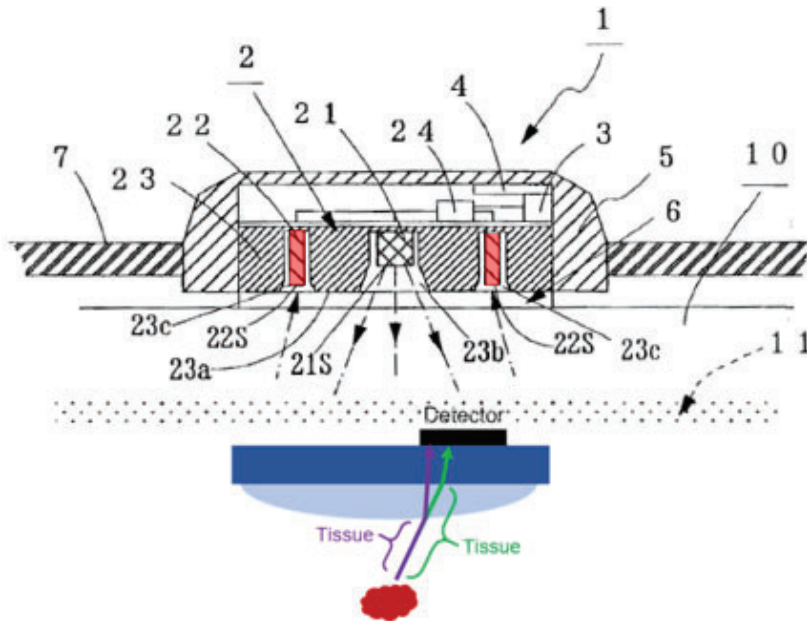
FIG. 1 (a)



Aizawa's Features

- **Green:** central emitter (21)
- **Red:** peripheral detector (22)

64. When discussing the change in light path for light interacting with a convex surface, Dr. Kenny's declaration does not use either Aizawa's structure or what Dr. Kenny asserts would have been the result of combining Aizawa and Inokawa. Instead of using Aizawa's actual structure (below, top), Dr. Kenny presents a separate figure (below, bottom) that drastically increases the size of a detector compared to Aizawa and eliminates the surrounding barriers.



Aizawa's figure illustrating detectors (22, red) (Ex. 1006 Fig. 1B)

Dr. Kenny's depiction drastically increasing size of Aizawa's detector (black) (Ex. 1003 ¶108)

65. Applying Dr. Kenny's illustration of the redirected light path (illustrated by the purple line in the second figure above) to Aizawa's actual detectors (highlighted in red in the first of the two figures above) confirms the redirected light would not even reach the detectors because it would miss both Aizawa's small detectors and even the slightly larger cavities due to passing through the convex surface. It appears that Dr. Kenny increased the size of Aizawa's detector approximately five-fold to so that the redirected light reached the detector, and also eliminated the opaque barrier of Aizawa's holder 23 entirely. There is no analysis or explanation of these changes in Dr. Kenny's declaration, or any acknowledgement that the redirection of light towards a more central location would have caused the redirected light to miss Aizawa's detectors entirely. *See*

Ex. 1003 ¶¶107-108 (No indication that size of Aizawa's detectors had to be changed in order to still detect light redirected by convex surface).

3. **Dr. Kenny's Testimony Further Undermines Obviousness**

66. Dr. Kenny's declaration includes figures that he describes as illustrating the phenomenon of how "the incoming light is 'condensed' toward the center," after interacting with a protruding surface. Ex. 1003 ¶¶107, 192; *see also* Ex. 2020 at 69-70. The term "condensing" in the context of light passing through a surface describes the general understanding of a POSITA that light is directed towards a more central location when passing through a protruding surface, and thus results in a relative increase of light at the center and decrease of light at the peripheral edge of underlying structure. I further note that the figures at paragraphs 107-108 in Dr. Kenny's declaration are used with respect to a limitation involving the "mean path length of light traveling to the at least four detectors." Ex. 1003 ¶¶106-108; *see also* Ex. 2020 at 69-71, 115-117. In particular, the limitation Dr. Kenny analyzed in that declaration is: "The noninvasive optical physiological measurement device of claim 11, wherein the light permeable cover is configured to reduce a mean path length of light traveling to the at least four detectors." Further, in my opinion, as discussed above, a POSITA would have believed that the protruding surface in Inokawa would have redirected more light

data processing and not sensor design. Training in data processing would not have prepared a POSITA for the type of design process identified by Dr. Kenny as needed to develop a working optical physiological sensor.

74. A POSITA would have understood that Inokawa's convex lens benefits Inokawa's sensor design with its center-located detector. Ex. 1008 ¶58, Fig. 2. In my opinion, a POSITA would have credited the teaching of Inokawa itself, which shows that a protruding surface directs incoming light towards the center. Ex. 1008 ¶58, Fig. 2. In contrast, I do not believe a POSITA would have been motivated to go through Dr. Kenny's extensive trial and error process to try and figure out whether Inokawa's protruding surface would have analogous benefits in a device with peripheral detectors and a central emitter. Instead, a POSITA would have taken Inokawa's teaching at face value, consistent with the general understanding of how light interacts with a protruding surface.

75. Thus, accounting for the possibility that a POSITA with no experience in optical physiological sensor design would nonetheless understand the wide ranging considerations identified by Dr. Kenny at his deposition in related IPRs, it is still my opinion that Inokawa does not establish a valid motivation to combine Inokawa with Aizawa, much less a reasonable expectation of success. When addressing a reasonable expectation of success, Dr. Kenny focuses his discussion on the manufacturing of a device, and not whether the device would be able to

successfully act as a physiological monitor or sensor. See, e.g., Ex. 1003 ¶¶86-87. Whether or not “the shape of the cover can be readily modified” (Ex. 1003 ¶86), Dr. Kenny never explains why a POSITA would have expected Petitioner’s proposed combination to result in a successful optical physiological sensor. The lack of analysis is particularly important because a POSITA would have expected a protruding surface to decrease the optical signal at the peripheral detectors. The possibility that POSITA could manufacture a device is not evidence a POSITA would have reasonably expected the resulting device to successfully work as an optical physiological measurement device. Decreasing the amount of light reaching the detectors will decrease the signal, increase the relative amount of noise, and could thus result in a signal unusable for actually monitoring a physiological parameter.

4. Petitioner’s Obviousness Challenge Also Relies On References Not Identified As Part Of Ground 1A Without A Motivation To Combine Or Expectation Of Success

76. I further note that the Petition, and Dr. Kenny’s analysis, apparently relies on references that neither the Petitioner nor Dr. Kenny identifies as part of Ground 1A. The Petition states that Ground 1A includes only two references: Aizawa and Inokawa. Pet. 1. But Dr. Kenny’s analysis relies on another cited reference: Nishikawa. Ex. 1003 ¶¶82-87.

92. Dr. Kenny thus explains the motivation for the proposed combination is: “a POSITA would have been motivated to incorporate the lens of Inokawa into to [sic] cover of Mendelson-1988 in order to increase the light collection efficiency.” Ex. 1003 ¶167. Dr. Kenny also asserts that the proposed combination modifies Mendelson-1988’s flat epoxy cover with “a curved one as per Inokawa.” Ex. 1003 ¶168. Dr. Kenny asserts that “The lens of Inokawa provides precisely this benefit to Mendelson-1988’s device by providing a protective cover that further refracts and concentrates the incoming light beams to thereby enhance the light collection efficiency.” Ex. 1003 ¶167.

93. As discussed in more detail below, I disagree that a POSITA would have believed that Inokawa’s protruding surface would have increased the amount of light reaching Mendelson-1988’s peripheral detectors. Likewise, I disagree that a POSITA would have understood that the “lens of Inokawa provides precisely this benefit to Mendelson-1988’s device” of increasing light collection efficiency, as Dr. Kenny asserts (Ex. 1003 ¶167).

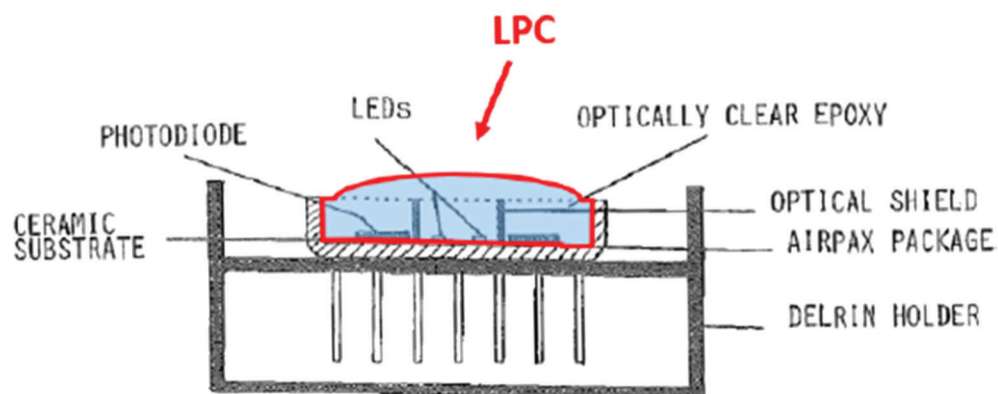
B. Ground 2A Does Not Establish Obviousness

1. Ground 2A Does Not Demonstrate A Motivation To Combine Mendelson-1988 And Inokawa, And Does Not Establish A Reasonable Expectation Of Success

94. The proposed combination of Mendelson-1988 and Inokawa suffers from the same problems as the proposed combination of Aizawa and Inokawa. In

the proposed Mendelson-1988-Inokawa combination, as in the proposed Aizawa-Inokawa combination, the detectors are on the periphery of the device. Ex. 1015 at 2, Figs. 2A-2B. As explained above, Inokawa's convex lens focuses light on a centrally located detector. See ¶¶42-61 and 66-75 of this declaration, above; *see also* Ex. 2020 at 115-117 (Dr. Kenny explaining that light passing through a convex surface is condensed towards the center relative to a flat surface). A POSITA would not have been motivated to incorporate a protruding surface to direct light away from the detectors for the same reasons discussed above. *See* ¶¶42-61 and 66-75 of this declaration, above.

95. As shown in Dr. Kenny's illustration below, the proposed combination of Mendelson-1988 and Inokawa positions detectors (Mendelson-1988's photodiodes) on the periphery of the sensor:



Dr. Kenny's illustration of the proposed combination of Mendelson-1988 and Inokawa (Ex. 1003 ¶172)

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UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

| | | |
|---------------------|---|--------------------------|
| APPLE INC., |) | |
| |) | IPR NO. 2020-1520 |
| Petitioner, |) | US PATENT NO: 10,258,265 |
| |) | |
| -against- |) | IPR NO. 2020-1537 |
| |) | US PATENT NO: 10,588,553 |
| MASIMO CORPORATION, |) | |
| |) | IPR NO. 2020-1539 |
| Patent Owner. |) | US PATENT NO: 10,588,554 |
| |) | |

VIDEO-RECORDED DEPOSITION OF
THOMAS WILLIAM KENNY, JR. PH.D.

VOLUME 1

Zoom Recorded Videoconference

04/22/2021

9:02 a.m. (Pacific Daylight Time)

REPORTED BY: AMANDA GORRONO, CLR
CLR NO. 052005-01

DIGITAL EVIDENCE GROUP
1730 M Street, NW, Suite 812
Washington, D.C. 20036
(202) 232-0646

Masimo Ex. 2006
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1 A. Part of that that's inside the, the
2 lens, yes, is refracted more towards the center,
3 because the location where it strikes the surface,
4 there is a different angle of incidence because of
5 the curvature of the lens.

6 Q. Let me ask you a little bit about
7 this claim limitation. If you want to turn back to
8 Page 69. You're discussing here, I think this is a
9 mean path length of light. Do you see that?

10 A. Uh-huh.

11 Q. I think you said a moment ago you
12 were calculating a path length. I guess I want to
13 ask you, how did you interpret mean path length for
14 your analysis?

15 MR. SMITH: Objection; form.

16 A. So my understanding is that this is a
17 particular but representative example path, and
18 that -- you know, if I'm thinking about what goes on
19 here, the two situations will have the same path
20 length if the angle of incidence is the same, whereas
21 because of the curvature of the lens, the curvature
22 provides a higher angle of incidence for most path

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1 length. So the refractive effect will lead to a
2 short mean of the path on average of the mean.

3 Q. So what you're showing here is
4 that -- so when --

5 MR. LARSON: Sorry, strike that.

6 Q. So what you're discussing here when
7 you say a mean path length, you're talking about the
8 path on average; is that is that fair?

9 MR. SMITH: Objection; form.

10 A. So a mean path length mean the same
11 as an average patent length, yeah.

12 Q. Is that how you're understanding it?

13 A. My understanding, yes, would be if I
14 repeated this analysis for a multitude of path
15 lengths, I would find that the majority of them would
16 have a shorter path length.

17 Q. If you go down to Paragraph --
18 Paragraph 119, you say, "In more detail, I noted
19 above for [1d] how the lens/protrusion of Inokawa,
20 which is used to modify Aizawa's cover, provides a
21 condensing function by refracting the light passing
22 through it."

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1 Q. And so with the convex shape in your
2 combination, I think you testified just now that
3 there would be a reduction in the amount of light at
4 the perimeter and an increase as you come underneath
5 the curvature towards the center; is that correct?

6 A. Maybe just to be precise, if you
7 looked across -- if you looked on the example on the
8 right and you had a way of measuring the light
9 intensity from centered all the way to edge and you
10 could do it for enough different examples of the
11 corpuscle arrangements that you could average out
12 those artifacts, you would see more light in the
13 center than at the outer edge in this example.

14 Q. And that's because light's being
15 directed towards the center and away from the edge,
16 correct?

17 A. Among other things, yes, that's a
18 part of why. Also, as we've discussed, this
19 protruding lens is able to capture more light coming
20 in at a weak angle that is additive to this effect.

21 Q. So it sounds like there's two
22 considerations here. One is the convex lens in

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1 a spherical example or this example or some other
2 examples there would be different amounts of these
3 two effects at different locations. So it's hard to
4 give a general accurate answer.

5 Q. Oh, and my question, to be clear, I'm
6 trying to have you focus on just one of the effects.
7 So just for the -- and, you know, you can go on and
8 provide more testimony, you can provide testimony
9 about the other fact that you sort of -- but focusing
10 just on the first effect, the fact that the convex
11 lens will direct more light toward the center means
12 that it will be directing more light away from the
13 sides, correct?

14 A. I think one of ordinary skill in the
15 art looking at this illustration on the bottom right
16 of Page 55 would understand that both effects are
17 present, but to the extent we're focused just on the
18 refraction effect and not the light capture effect,
19 that the, the distribution of light on that surface
20 would be shifted from the edge towards the center
21 somewhat depending on the details of the shape.

22 Q. Let me ask you about the -- this